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**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

Docket No. 15-17

**Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy
Decision and Order**

On February 23, 2015, the former Deputy Assistant Administrator of the then-Office of Diversion Control, Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause to Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy (hereinafter, Respondent). ALJX 1. The Show Cause Order proposed the revocation of Respondent's registration pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f) on the ground that Respondent's registration is inconsistent with the public interest. ALJX 1, at 1. For the same reason, the Show Cause Order also proposed the denial of any pending application by Respondent for renewal or modification of its registration, and the denial of any application by Respondent for any other DEA registration. *Id.* (citing 21 U.S.C. § 823(f)).

As the jurisdictional basis for the proceeding, the Show Cause Order alleged that Respondent's DEA Certification of Registration No. FP1049546 authorized it to dispense controlled substances in schedules II through V as a retail pharmacy at the registered location of 205 E. Hallandale Beach Blvd., Hallandale Beach, Florida 33009. *Id.* Respondent's registration was to expire on March 31, 2017. *Id.*

As the substantive grounds for the proceeding, the Show Cause Order contained seven categories of violations. First, it alleged that "Zion dispensed controlled substances where it knew, or should have known, that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose and therefore failed to exercise its

corresponding responsibility regarding the proper prescribing and dispensing of controlled substances.” *Id.* (citing 21 CFR 1306.04(a)). The Show Cause Order stated that Respondent’s failure to exercise its corresponding responsibility was evidenced by its “dispensing of controlled substances despite the presence of red flags of diversion that Zion failed to clear prior to dispensing the drugs.” *Id.* at 1-2. The Show Cause Order listed seven red flags of diversion that Respondent allegedly did not resolve prior to filling prescriptions. *Id.* at 2-7. It cited *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 FR 62,316 (2012) (hereinafter, *Holiday CVS*) as support for these allegations.

The Show Cause Order listed 13 prescriptions, for customers who allegedly traveled long round-trip distances of approximately 166 to 661 miles from home to physician to Respondent and back home, and alleged that Respondent filled them without having resolved the long distance red flags of diversion. ALJX 1, at 2-3. Each of the 13 prescription examples was for a controlled substance written some time during the period of February 2012 through January 2013. *Id.*; *see also* Government Exhibit (hereinafter, GX) 8/8a.

The Show Cause Order cited five prescriptions written by the same doctor on June 27, 2012 for five different customers for “1 ML Testosterone Cypionate 210mg/mL IM,” a controlled substance, that Respondent allegedly filled without first having resolved the red flags of diversion. ALJX 1, at 3-4; *see also* GX 10.

The Show Cause Order referenced two prescriptions for Dilaudid 8 mg., a controlled substance, written by the same doctor on June 22, 2012 for two individuals with the same last name and the exact same street address that Respondent allegedly filled without first having resolved the red flags of diversion. ALJX 1, at 4; *see also* GX 11. The Show Cause Order

alleged that Respondent filled the two prescriptions on July 13, 2012 at 2:35 pm and 2:39 pm, respectively. ALJX 1, at 4.

The Order to Show Cause alleged that Respondent filled two prescriptions for the same customer on the same day for the same immediate release controlled substance, but for different strengths, without first having resolved the red flags of diversion. *Id.* The two pairs of prescriptions listed in the Show Cause Order to illustrate this allegation were issued for Dilaudid 8 mg. and Dilaudid 4 mg. *Id.*; *see also* GX 12. They were written during the period of September 2012 through November 2012. ALJX 1, at 4.

The Show Cause Order alleged that Respondent filled opiate (hydromorphone) and benzodiazepine (alprazolam, clonazepam, diazepam, or lorazepam) prescriptions, a “common ‘drug cocktail’ popular with drug abusers,” for the same customer on the same day at about the same time without first having resolved the red flags of diversion. *Id.* The Show Cause Order cited 14 prescriptions, or seven pairs of “drug cocktail” prescriptions, that Respondent allegedly filled during the period of October 2012 through January 2013. ALJX 1, at 4-5; *see also* GX 13.

The Order to Show Cause alleged that “[c]ustomers paying for their prescriptions with cash, where other red flags of diversion were present,” were red flags of diversion that Respondent did not resolve prior to having filled the prescriptions. ALJX 1, at 5. The Show Cause Order listed 50 examples of prescriptions paid for with cash, costing as much as \$1,008 for one prescription. *Id.*; *see also* GX 8, GX 10, GX 11, and GX 13.

The Show Cause Order alleged that Respondent filled prescriptions for “[c]ustomers [who] present[ed] new prescriptions for controlled substances when they should not have finished their previous prescription for that drug (‘early fills’ or ‘early refills’)” without first having resolved the red flags of diversion. ALJX 1, at 5. The Order to Show Cause provided

seven sets of examples of prescriptions that Respondent allegedly filled as many as 15 days early. *Id.* at 5-7; *see also* GX 14. The Show Cause Order specifically cited *Holiday CVS*, 77 FR at 62,318 as precedent for this charge. ALJX 1, at 7.

Next, the Order to Show Cause alleged that Respondent “was unable to readily retrieve prescriptions it had dispensed.” *Id.* (citing subsections (a) and (h)(3) and (4) of 21 CFR 1304.04). Specifically, the Show Cause Order alleged that, on April 11, 2013, DEA investigators conducted an on-site inspection of Respondent and requested specific prescriptions that Florida’s Prescription Drug Monitoring Program showed Respondent had filled.¹ *Id.* The Show Cause Order listed 12 testosterone prescriptions that Respondent filled from February 2012 through January 2013 and DEA investigators requested, but that Respondent’s staff was allegedly “unable to produce.” *Id.* at 7-8.

The Show Cause Order further alleged that Respondent filled controlled substance prescriptions and shipped them to Alabama, Georgia, Illinois, Kentucky, Massachusetts, and Vermont without meeting the out-of-state pharmacy requirements of four of those states.² *Id.* at 8. It detailed eight prescriptions that Respondent allegedly filled and shipped out-of-state, though it did not allege that all eight were shipped in violation of a State’s non-resident pharmacy requirements. *Id.* at 8-9; *see also* GX 15.

The Order to Show Cause next alleged that Respondent filled controlled substance prescriptions that did not contain all of the required information, such as directions for use, patient address, prescriber name, prescriber address, prescriber DEA number, and prescriber

¹ Florida’s Prescription Drug Monitoring Program is called the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (hereinafter, E-FORCSE).

² The Order to Show Cause cited the allegedly violated state legal requirements as Alabama: Rules of Ala. State Bd. of Pharm. § 680-x-2-.07(2); Illinois: Ill. Admin Code tit. 68, § 1330.550(a); Kentucky: Ky. Rev. Stat. § 315.0351(1); and Vermont: Admin. Rules Vt. Bd. of Pharm., Part 16.

signature. ALJX 1, at 9 (citing 21 CFR 1306.05(a) and (f)). It specified eight prescriptions and the required information each one allegedly lacked. *Id.* at 9-10; *see also* GX 16.

Next, the Show Cause Order alleged that Respondent filled prescriptions written for “office use” in violation of 21 CFR 1306.04(b). ALJX 1, at 10. It provided two examples of such prescriptions. *Id.* at 10; *see also* GX 17.

The Show Cause Order also alleged that Respondent filled prescriptions written by physicians for their personal use in violation of Florida law. ALJX 1, at 10 (citing Fla. Stat. § 458.331(r)). It referenced six examples of prescriptions where the name of the prescribing physician was the same name as the patient. *Id.*; *see also* GX 18.

And, lastly, the Order to Show Cause alleged that Respondent violated Florida law by “failing to report some prescriptions to E-FORCSE, in violation of Fla. Stat. § 893.055(4).” ALJX 1, at 10. It listed six prescriptions that Respondent allegedly did not report to E-FORCSE. *Id.* at 11; *see also* GX 19.

The Show Cause Order notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. ALJX 1, at 11 (citing 21 CFR 1301.43).

On February 25, 2015, the DEA Diversion Investigator (hereinafter, DI) assigned to the investigation of Respondent, personally served the Order to Show Cause on Respondent’s owner and operator, Veronica Taran (hereinafter, Respondent’s Owner and PIC).³ ALJX 5

³ She variously testified that she was “the owner of the respondent pharmacy” and that she was “an owner and a Pharmacist-in-Charge” of Respondent. Transcript Page (hereinafter, Tr.) 795, 798 (respectively); *see also* Stipulation No. 2, ALJX 10, at 1.

(Government's Prehearing Statement dated March 27, 2015 (hereinafter, Govt. Prehearing Statement)), at 2; ALJX 7 (Respondent's Prehearing Statement dated April 10, 2015), at 2; *see also* Stipulation No. 4, ALJX 10, at 2.

By letter from its attorneys dated March 12, 2015, Respondent timely requested a hearing and asked that a "reasonable extension to respond to an Order to Show Cause" be granted. ALJX 3 (Hearing Request dated March 12, 2015), at 1; ALJX 4 (Order for Prehearing Statements dated March 17, 2015), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). On March 17, 2015, the CALJ established the schedule for the filing of prehearing statements and granted Respondent's request for additional time "to the extent that the hearing date set in the OSC ... will be continued as directed at the prehearing conference scheduled by this order." ALJX 4 (Order for Prehearing Statements), at 1, 2.

On March 27, 2015, the Government filed its Prehearing Statement. ALJX 5. On April 10, 2015, Respondent served its Prehearing Statement. ALJX 7. The April 14, 2015 Prehearing Ruling and Protective Order found that four "stipulations have been mutually agreed to and are conclusively accepted as facts." ALJX 10, at 1.

On May 6, 2015, the Government and Respondent filed Supplemental Prehearing Statements. ALJX 6 and ALJX 9, respectively. The parties' joint filing dated May 26, 2015 included their 11 additional joint stipulations. ALJX 20, at 1-2.

On June 9 through 11, 2015 and on August 4, 2015, the CALJ conducted an evidentiary hearing in Miami, Florida. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated October 16, 2015 (hereinafter, R.D.), at 2. At

Her testimony cited in this Decision and Order is quoted verbatim from the hearing transcript, without correction or "[sic]" notations in addition to those already in the transcript.

the hearing, both parties called witnesses to testify and offered documents into evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, proposed conclusions of law, and argument.

On October 16, 2015, the CALJ issued his Recommended Decision, including that all but two of the Show Cause Order's allegations, the sixth (prescriptions written for "office use") and the seventh (prescriptions written for the prescriber's personal use), be sustained. *Id.* at 33-36, 38-39 (respectively). Regarding those two allegations, the CALJ's recommendations were that there were substantive violations, but that the allegations should not be sustained "based exclusively on the lack of adequate notice under current Agency precedent." *Id.* at 36, 39 (respectively).

The CALJ found that the Government "supplied sufficient evidence to make out a *prima facie* case." *Id.* at 57. He also found that Respondent's acceptance of responsibility was insufficient. *Id.* at 58. Concerning remedial steps, he explained that Respondent's "intentional decision to decline to notice evidence of remedial steps resulted in their preclusion from consideration." *Id.* In sum, he concluded that the record supported imposition of a sanction. *Id.*

The CALJ included in his R.D. an assessment of the degree and extent of Respondent's misconduct and concluded that Respondent had not "accepted anything meaningful in terms of responsibility or learned anything." *Id.* at 59. "Where no understanding is acquired about how the regulated conduct fell short of professional and federal and state legal standards," he wrote, "it would be difficult (even illogical) to predict improvement." *Id.* He determined that the Registrant "is likely to proceed in the future as it has in the past if not curtailed in its ability to do so." *Id.* He concluded that the "sheer number of established transgressions of various types, coupled with the refusal to admit that issues existed, would render a sanction less than revocation

as a message to the regulated community that due diligence is not a required condition precedent to operating as a registrant.” *Id.* at 59. He recommended revocation of Registrant’s registration and the denial of any pending applications for renewal. *Id.* at 60.

On November 5, 2015, both parties filed Exceptions to the R.D. Respondent served supplemental Exceptions to the R.D. on November 16, 2015. By letter dated November 10, 2015, the record was forwarded to me for Final Agency Action.⁴

Having considered the record in its entirety, including all of the Exceptions filed by Respondent and the Government, I agree with the CALJ that Respondent’s registration should be revoked and that any pending applications for its renewal or modification should be denied. I further agree with the CALJ’s conclusions that Respondent dispensed controlled substances knowing that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose and, therefore, violated the corresponding responsibility rule of 21 CFR 1306.04(a). I agree with the CALJ that Respondent was unable to readily retrieve prescriptions it had dispensed and, therefore, violated 21 CFR 1304.04. I agree with the CALJ that Respondent filled controlled substance prescriptions and shipped them out-of-state in violation of four States’ non-resident pharmacy requirements. I agree with the CALJ that Respondent violated 21 CFR 1306.05 by filling controlled substance prescriptions that did not contain all of the required information. Based on Respondent’s admissions, I find that Respondent filled prescriptions written for “office use,” although I do not sustain this allegation due to the Government’s failure to comply with the notice requirements for a Show Cause Order. 21 CFR 1301.37(c). I find that Respondent filled at least one controlled substance prescription

⁴ By correspondence dated February 29, 2016, Respondent’s counsel gave notice of “termination of legal representation and an attorney/client relationship with the Respondent.”

written by a physician for the physician's personal use, although I do not sustain this allegation due to the Government's failure to comply with the notice requirements for a Show Cause Order. 21 CFR 1301.37(c). I agree with the CALJ's conclusion that Respondent failed to report controlled substance prescriptions to E-FORCSE in violation of Fla. Stat. § 893.055(4) (2012). I agree with the CALJ that Respondent's acceptance of responsibility was insufficient and that Respondent did not provide sufficient notice of remedial measures.

Accordingly, I find the record as a whole established by substantial evidence that Respondent committed acts which render its continued registration inconsistent with the public interest. I conclude that revocation of Respondent's registration and denial of any pending application to renew or modify Respondent's registration are appropriate sanctions. I make the following findings.

FINDINGS OF FACT

Respondent's DEA Registration

Respondent is registered with the DEA as a retail pharmacy in schedules II through V under DEA Certificate of Registration No. FP1049546 at 205 E. Hallandale Beach Blvd., Hallandale Beach, Florida 33009. ALJX 1, at 1; *see also* Stipulation No. 1; ALJX 10, at 1. Respondent's registration was to expire on March 31, 2017. Stipulation No. 1; ALJX 10, at 1. According to DEA's registration records, however, on January 31, 2017, Respondent timely filed a renewal application. I take official notice of that pending registration renewal application. 5 U.S.C. § 556(e).⁵ Respondent's registration, therefore, remains in effect pending the issuance of this Decision and Order. 5 U.S.C. § 558(c).

⁵ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding – even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. §

The Investigation of Respondent

According to the testimony of the DI, he decided to investigate Respondent after learning that it had ordered 41,700 dosage units of hydromorphone in 2012. Tr. 28. This raised his suspicion because the average pharmacy in the United States ordered approximately 5,900 dosage units of hydromorphone in the same time period. *Id.* at 28.

On April 11, 2013, the DI presented Ms. Veronica Taran, Respondent's Owner and PIC, with a Notice of Inspection. *Id.* at 38; *see also* Stipulation No. 3; ALJX 10, at 2. The DI testified that Respondent's Owner and PIC read the notice of inspection, did not have any questions for the DI about it, signed it, and consented to the inspection. Tr. 38. The DI then asked Respondent's Owner and PIC for various records, including order forms and prescriptions filled for schedule II through V controlled substances. *Id.* The DI stated that "I asked Mrs. Taran if we could take records for further review, so we boxed them up and took them with us. She consented to that." *Id.* at 52-53. When he left Respondent on the unannounced inspection day, he took with him "2011 to 2013 Schedule II through V prescriptions, ... any invoices or receipts covering the same timeframe, and executed DEA 222 forms and ... [Respondent's] biennial inventory." *Id.* at 50.

The DI also testified about approximately a dozen problematic prescriptions he had identified from E-FORCSE that Respondent's Owner and PIC "was never able to locate ... for me." *Id.* at 42, 43. "They were written for different anabolic steroid substances to patients that were not in the State of Florida," he testified. *Id.* at 42.

556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Respondent or the Government may dispute my finding by filing a properly supported motion for reconsideration within 10 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the other party; in the event either party files a motion, the other party shall have 10 calendar days to file a response.

The DI testified that he asked Respondent's Owner and PIC questions, including how she would verify controlled substance prescriptions. *Id.* at 39. According to the DI, Respondent's Owner and PIC said that she used two forms, one to verify the prescription and a doctor-patient affidavit "that she makes the patient fill out," and she checked the prescriber's DEA number on the DEA website and the prescriber's license on the Florida Department of Health website. *Id.* at 39-40. According to the DI, Respondent's Owner and PIC told him that she was familiar with her patients and visited the doctors and their offices. *Id.* at 40.

The DI testified that Respondent's Owner and PIC had posted lists: "[o]ne was for doctors she would fill prescriptions for, another list of doctors that she wouldn't fill prescriptions for, and ones that were pending verification." *Id.* at 40; *see also id.* at 41. The DI stated that Respondent's Owner and PIC specifically told him "she does not check" E-FORCSE, she had never shipped a controlled substance out of state, and "the pharmacy was not licensed in any other state." *Id.* at 40-41, 44. Regarding E-FORCSE, the DI testified that he asked Respondent's Owner and PIC to "go onto" it to "check a prescription for me" and that "she wasn't able to do that." *Id.* at 48-49. When asked for elaboration on the meaning of "she wasn't able to do that," the DI responded that she did not have access. He testified, "She had access to enter her data into, but not to query a patient. ... I was standing next to her when she was logged onto the computer attempting to query a patient." *Id.* at 49.

The Allegations of Dispensing and Non-Dispensing Violations

The Order to Show Cause alleged seven bases for the revocation of Respondent's registration pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f). One of them had seven subparts.

Witnesses

Four witnesses testified at the hearing: the DI and Dr. Tracey J. Gordon for the Government, and Louis Fisher and Respondent's Owner and PIC called by Respondent. There was factual agreement among the witnesses on a number of issues. When there was factual disagreement, I applied the CALJ's credibility recommendations. *See* R.D., at 5-25.

Regarding the DI, the CALJ stated that he "presented as an objective regulator with no stake in the outcome of the proceedings" and provided "testimony [that] was sufficiently detailed, plausible, consistent, and cogent to be fully credited." R.D., at 8. I agree with the CALJ's assessment of the DI's credibility.

At the hearing, the Government also offered testimony from Dr. Tracey Gordon, a pharmacist licensed in Florida who had practiced pharmacy for 21 years. Dr. Gordon testified to "ten-plus years of retail" experience in "at least 200" Florida retail pharmacies serving as a clerk, tech, intern, assistant manager, and manager. Tr. 282, 284. She testified to having experience dispensing controlled substances for the treatment of chronic pain. *Id.* at 289. She stated that she has served as a pharmacist-in-charge. *Id.* at 351. She testified to training in, and experience with, issues regarding the use and diversion of controlled substances, and to familiarity with the pharmaceutical practice aspects of the use and abuse of controlled substances. *Id.* at 289-90. She stated that she was a licensed Consultant Pharmacist and, at the time, was serving as a clinical Hospice pharmacist. *Id.* at 278-79.

Dr. Gordon was accepted, without objection, "as an expert in the practice of pharmacy in the [S]tate of Florida regarding the dispensing of controlled substance prescriptions." R.D., at 8; *see also* Tr. 294-95.⁶ The CALJ found that Dr. Gordon's testimony was "internally consistent

⁶ On cross-examination, Respondent elicited that, although Dr. Gordon had helped her father in his store before she was a pharmacist, she never worked as a pharmacist in a small independent pharmacy. Tr. 477-78. Respondent further elicited that Dr. Gordon was "never in charge of purchasing controlled substances for resale for a small

and logically persuasive” and her qualifications “reflected a wide breadth of pharmacy experience, including working in many pharmacies as a line pharmacist and a pharmacist in charge,” and as a consultant and teacher. R.D., at 11. I agree with the CALJ that Dr. Gordon’s “answers rang of sufficient clarity, authority, and candor to merit controlling weight in these proceedings regarding the practice of pharmacy in Florida.” *Id.* at 11.

Respondent offered the testimony of Louis Fisher, who graduated in 1971 from the Hampden College of Pharmacy and worked for DEA or its predecessor agency from 1971 to 2003. Tr. 565. Mr. Fisher testified that, during his government service, his positions included compliance investigator, quota operation staff assistant, diversion investigator, diversion program manager, and group supervisor. *Id.* at 565, 570. He stated that he was “familiar with a procedure of dispensing controlled medications pursuant to prescriptions in Florida,” even though he never practiced pharmacy, or was a licensed pharmacist, in Florida. *Id.* at 571-72, 574-75. He testified that he was a consultant in the field of “controlled substances abuse and diversion” at the time. *Id.* at 572. Respondent sought to qualify Mr. Fisher as a “specialist in preventing drug diversion.” *Id.* at 561.

The CALJ accepted Mr. Fisher as an expert on the issue of dispensing in Florida. R.D., at 11 n.74, at 17. I agree with the CALJ that it is appropriate to “afford ... diminished weight [to

independent pharmacy.” *Id.* at 482. Respondent’s first Exception to the R.D. also asserts “[a]s evident from the record” that “Respondent challenged Dr. Gordon’s qualifications to testify about dispensing patterns ... for a small sized, independent pharmacy such as Respondent.” Respondent’s Exceptions to the ALJ’s Recommended Ruling dated Nov. 5, 2015 (hereinafter, Resp. Exceptions), at 2. Respondent did not, however, provide a citation to the record for its assertion and my review found none. 21 CFR 1316.66(a). Regardless, given that the Show Cause Order did not raise “dispensing patterns ... for a small sized, independent pharmacy,” Respondent’s assertion is not germane to the resolution of this matter.

Mr. Fisher's testimony] where it conflicts with other, more persuasive evidence of record, including the testimony of Dr. Gordon."⁷ *Id.* at 17; *see also id.* at 11 n.74.

At the hearing, Respondent also offered testimony from Respondent's Owner and PIC. Tr. 798. Respondent's Owner and PIC testified that she had been, at the time, a practicing pharmacist in Florida for about ten years. *Id.* at 798. She testified that she was familiar with the Florida provision specifically addressing the dispensing of controlled substances, and that she had taken "[m]ultiple courses" on "red flag of diversions" as well as "read many articles online about the situation in Florida with the pain management." *Id.* at 799. Respondent's Owner and PIC also testified that she was a custodian of records for Respondent and supervised, at the time, one technician, one intern, and one student. *Id.* at 798-99.

I agree with the CALJ's conclusion that, while "[t]here were, undoubtedly, aspects of ... [the testimony of Respondent's Owner and PIC] during which she presented as generally credible, ... on the present record, her testimony was not sufficiently consistent or plausible to be afforded full credibility." R.D., at 25.

Florida Pharmacists' Standard of Practice

Dr. Gordon, Mr. Fisher, and Respondent's Owner and PIC testified about a Florida pharmacy's/pharmacist's standard of practice when presented with a controlled substance

⁷ The CALJ explained that Mr. Fisher's "discrepant testimony regarding his licensure and experience was disquieting. ... On this record, the issue of Mr. Fisher's qualifications to render an expert opinion is uniquely dependent upon his own representations of his experience and, thus, his credibility. Either Mr. Fisher was careless ... and reckless ..., or he was engaged in an intentional effort to inflate his own qualifications. Either option undermines the weight that can be logically afforded to his opinions, and where these opinions conflict with other opinions or evidence, they cannot be relied upon." R.D., at 16 (footnote omitted).

prescription.⁸ There were some areas of agreement by at least two of the three witnesses on some aspects of that standard.

According to Dr. Gordon, upon a customer's presentation of a controlled substance prescription, the pharmacist should protect the safety of the patient and the community by looking for red flags of diversion, or "something that makes a pharmacist pause and think about" whether the prescription was "really for a legitimate medical purpose." Tr. 296, 303. She discussed red flags including the quantity and dosage of the controlled substance, the doctor and practice specialty, and the patient's geographic location, doctor/pharmacy patronage, and payment (insurance/cash) method. *Id.* at 295-97.

Regarding the quantity and dosage of a controlled substance used for pain management, Dr. Gordon explained that "I look ... [for] a long-acting with the prescription ... [because] [i]t helps the patient to be more adherent to therapy." *Id.* at 296.

Regarding the doctor and practice specialty, Dr. Gordon explained that, "I feel pretty comfortable filling a prescription for a large quantity of pain medication" if an oncologist wrote it. *Id.* at 298. "But if it's from a general practitioner or an ob-gyn," she continued, "then that causes me to take pause and reevaluate the legitimacy of the prescription." *Id.* She testified that the National Provider Identification website showed physicians' specialties and helped the pharmacist evaluate prescriptions. *Id.* at 297-98, 345. She also testified that a pharmacist should routinely check the status of a controlled substance prescriber's State medical license and DEA registration. *Id.* at 301, 345.

⁸ The DI also addressed the standard of practice. For example, he testified that his investigation identified issues concerning Respondent's compliance with the Controlled Substances Act and its implementing regulations. *See, e.g.*, Tr. 51, 54, 68, 71, 73, 74-75, 76-77, 99, 102, and 124.

Regarding the patient, Dr. Gordon stated that a chain pharmacy's computer would show if the customer had filled the prescription at another branch, and Florida's prescription drug monitoring program, E-FORCSE, would show what other controlled substances the customer had received from other pharmacies or doctors. *Id.* at 301-02, 345. She explained that E-FORCSE "gives you the date ... [the prescription] was written, the date it was filled, the name of the drug, the quantity, the doctor, the pharmacy, and how the patron paid for the medication" which would tell the pharmacy "if the patient was either doctor-hopping or pharmacy-hopping." *Id.* at 302.

Dr. Gordon testified about the importance of the customer's payment method, explaining that "[a] lot of drug-seekers only want to pay for their medications in cash because ... the insurance company will actually create your red flag for you to say if a prescription is refilled too soon, which means they've ... obtained a prescription from another pharmacy." *Id.* at 297; *see also id.* at 298-99.

Dr. Gordon stated that what constituted a red flag "changed all the time. It's like the drug community gets smarter." *Id.* at 303. She indicated that, when confronted with a red flag, a pharmacist would make further inquiries of the doctor, the customer, or the caregiver. *Id.* at 305. She noted that "some of the red flags really can't be resolved, especially if you see patterns." *Id.* at 304-05. She testified that, if she could not resolve a prescription's red flags, she would not fill it. *Id.* at 305. She would either give the prescription back to the customer or, with the doctor's authorization, shred it. *Id.*

Dr. Gordon testified that, although there is no codified Florida rule specifying where a pharmacist must document resolution of a red flag, the standard practice in Florida was for the resolution of a red flag to be documented on the front of the prescription. *Id.* at 346-48. As a

pharmacist-in-charge, she would check the face of the prescription to see if a subordinate pharmacist resolved a concern about the prescription. *Id.* at 351-52. She testified that any notes about the patient, as opposed to notes about a specific prescription, would appear in the patient profile. *Id.* at 350, 352.

Mr. Fisher testified that red flags “are part of the pharmacist’s responsibility.” *Id.* at 616. Regarding what a pharmacist should do to resolve a red flag, Mr. Fisher first stated that the pharmacist should “[c]heck the state E-FORCSE system to see if this person is a doctor-shopper.” *Id.* at 604; *see also id.* at 608-09. He also stated that he would check the doctor’s license to make sure it was valid, check if the customer had any history in the pharmacy of previous prescriptions being filled, and “then talk to the doctor and see ... what the – maybe the diagnosis is on this prescription.” *Id.* at 604. When asked “where would you see if these things were done, if they were documented,” Mr. Fisher responded that the documentation could be written on the back of the prescription, in a notebook, in a logbook “of any kind” or “whatever system they want to be put into effect.” *Id.* at 604-05. When asked whether the red flags “would have to be documented someplace,” Mr. Fisher responded affirmatively. *Id.* at 605; *see also id.* at 598-600 (Mr. Fisher’s testimony that a pharmacist needs to resolve a red flag before dispensing the prescription, and resolution of the red flag must be documented somewhere.). Mr. Fisher testified that he did not know if the red flags he had identified on the prescriptions in the Government’s exhibit had been resolved. *Id.* at 605; *see also id.* at 766 (Mr. Fisher’s testimony that the prescriptions contained no notations evidencing that Respondent had resolved any of their red flags.).

The testimony of Respondent’s Owner and PIC about diversion and what a pharmacy needed to do when presented with a controlled substance prescription was largely inconsistent

with the testimony of Dr. Gordon and Mr. Fisher. Further, her testimony admitted that Respondent did not even follow the steps she described. It also, though, evidenced her knowledge and awareness that schedule II controlled substances were prone to diversion. For example, Respondent's Owner and PIC testified that "[e]ach prescription it comes with chronic nonmalignant pain, has to be addressed as a highly risky – high risk medication. It has to be addressed with proper steps." *Id.* at 1129. Also regarding prescriptions for schedule II controlled substances, she testified that "on schedule II, each time it's presented it has to be – there's a lot of diversion." *Id.* at 1116. Specifically, Respondent's Owner and PIC identified Dilaudid 8mg. and Dilaudid 4 mg. prescriptions as "highly risky." *Id.* at 1129; GX 12, at 5 and 7. When asked whether she recalled identifying "any red flags" when she filled a prescription for 174 tablets of Dilaudid 8 mg., Respondent's Owner and PIC responded that "the major red flag of that prescription is for Schedule II medication, Dilaudid, 8 milligram. Also, prescribed on the quantities." Tr. 880-81.

According to Respondent's Owner and PIC, Respondent, and she as its PIC, needed to implement specific procedures unique to schedule II prescriptions due to the diversion associated with them. Her "specific procedures" consisted of a series of steps. *See id.* at 883- 897 (using as an example GX 19, at 1). First, according to her testimony, she would "talk to doctor on each [schedule II] prescription" because "there's a lot of diversion" of schedule II controlled substances. *Id.* at 1116. Her testimony underlined the importance of talking to the prescribing doctor "each time" a schedule II prescription was presented by comparing the diversion of schedule II controlled substances with schedule III controlled substances:

When all the schedule II prescriptions – I would talk to doctor on each prescription. On schedule III I would talk to doctor when there's initial

prescriptions for it. But there's not that much schedule III situations. But on schedule II, each time it's presented it has to be – there's a lot of diversion.

Id.

Respondent's Owner and PIC described the conversation she had regarding the first prescription in GX 19, a prescription for 174 tablets of Dilaudid 8 mg. She stated that she called the office and asked to speak with the doctor. "[H]onestly," she admitted, the "doctor not always were available. But I spoke with the manager." *Id.* at 895. The "honest" admission of Respondent's Owner and PIC that she did not always speak with the prescribing doctor about a schedule II prescription contradicted other testimony she gave that she always spoke with the doctor regarding such prescriptions. *See, e.g., id.* at 1116.

Respondent's Owner and PIC continued to describe her conversation with the doctor's office. She testified that she "would ask a manager to tell me more what was happening with the patient; was he seen on that day?" *Id.* at 895.

So if the patient was seen on the day that the prescription was issued, and the quantity – the reason why he had prescribed that quantity this month? And they would tell me that he has diagnosis in the proper – that doctor has a note in his chart to consider alternative treatments. ... I would ask them, What did you prescribe today for that patient? ... So they have to spell out what did they write this day, the quantity, to make sure there is no alteration on the way – there is no forging of the prescription. Then I would say, Is it okay for me to fill it? And they would give me approval to fill.

Id. at 896. Respondent's Owner and PIC testified that after these steps, including "verify[ing] all the information, the address, the phone number, the complete date of birth, the doctor DEA number on the front, the quantities and the medications, the signature ... [a]nd that medication was hand signed by the doctor," she filled the prescription. *Id.* at 897.

Despite her testimony and her stated awareness of the high risk nature of schedule II prescriptions and the risk of diversion associated with them, including the "red flag" of

schedule II controlled substances being prescribed in large quantities, Respondent's Owner and PIC again admitted that she did not always follow her first step. Instead, she testified that she would have to "go one-by-one each [schedule II] prescription" before answering questions about whether or not she spoke with the doctor about any of them. *Id.* at 1137; *see also id.* at 1133-39. Thus, Respondent's Owner and PIC admitted more than once to not implementing her own requirement of speaking to the prescriber of every schedule II prescription.⁹ In making this admission, she did not explain why she deviated from her own procedure. Nor did she justify that deviation.

Second, Respondent's Owner and PIC testified that she made sure the prescriber's State medical license was active, and the prescription was within the scope of the prescriber's DEA registration. Regarding a prescriber's State license, she testified that she would make sure that "the doctor actually licensed in the State of Florida to prescribe controlled substances."¹⁰ *Id.* at 894. Regarding a DEA registration, she testified that she "was instructed ... [by DEA] to go on the website – diversion site and verify the

⁹ In the context of describing the uses of the "approved" stamp and the name/telephone number stamp, Respondent's Owner and PIC also testified she verified that the prescriptions were issued within the scope of the prescriber's practice when she talked "to the [prescriber's] office." Tr. 1132.

[The stamps mean that] I talk to the office and I spoke with the patient. And I fill out documentation appropriate for – I verified – and most important, I verified this prescription was issued within scope of the doctor's practice. The doctor was allowed to treat chronic pain. It was the scope of his practice. He made the decision to write this prescription according to his practice.

Id. at 1132-33; *contra id.* at 1225-27. It is noteworthy that Respondent's quoted testimony concerned her calling "the office" as opposed to her "speak[ing] with the doctor." *Id.* at 1138, 1132, respectively. It was the further admission of the Respondent's Owner and PIC that she did not always "speak with the doctor" as she had testified was appropriate due to the high risk nature of schedule II prescriptions and the risk of diversion associated with them. Given her testimony that she did not necessarily speak with the "doctor" about schedule II prescriptions, it also raises the question of whether Respondent's Owner and PIC actually "verified" that prescriptions were "issued within [the] scope of the doctor's practice." *Id.* at 1133.

¹⁰ Regarding the doctor who prescribed the first prescription in GX 19, Respondent's Owner and PIC testified that he was "licensed in the State of Florida to prescribe medication for chronic pain management." Tr. 894-95. "He was actually special trained in the pain management," she stated. *Id.* at 895.

physician DEA number” and “[s]ince that instruction I religiously did that.” *Id.* at 892; *see also id.* at 1131-32 (Pharmacies should “make sure that ... [the] doctor[] ... [was] legitimate, I mean, ... has a DEA license.”).

According to Respondent’s Owner and PIC, “[t]he decision of prescribing lies upon the physicians and the state who govern his practice.” *Id.* at 1108. She elaborated, asserting that a pharmacy must fill a controlled substance prescription issued by a practitioner with the appropriate State and DEA licenses unless there is “a very good reason not to fill it.” *Id.* at 1168.

The doctor tells you it’s okay to fill, just by the filling – the filling prescription. When the patient comes to the office – to the doctor, he’s seen by the doctor. Doctor asking how many pills you have, what are you taking? Then he decide to issue another prescription. Once he issue the prescription, it’s an order for a pharmacy- -- keep in mind, we still working in the medical system here. The prescription is an order for the pharmacist to fill. For me not to fill that prescription, I have to have a very good reason not to fill it, because it’s an order from the doctor to me to fill that prescription for that patient.

Id. at 1167-68. Respondent’s Owner and PIC did not explain what she meant by “a very good reason not to fill it.” Nevertheless, I found in the record evidence of numerous controlled substance prescriptions that Respondent’s Owner and PIC admitted Respondent filled without having documented the existence or resolution of any of the red flags of diversion identified in the testimony of Dr. Gordon and Mr. Fisher.

Third, Respondent’s Owner and PIC testified that her “main concern would be if this patient was checked and have relation with the doctor.” *Id.* at 885. In the context of GX 19, the six Dilaudid 8 mg. prescriptions the Show Cause Order alleged that Respondent did not report to E-FORCSE, Respondent’s Owner and PIC testified about how she would establish the requisite

doctor-patient relationship.¹¹ She testified that she would “ask ... [the customers] to fill out the [“Pain Management Physician-Patient Relationship Affidavit,” hereinafter, Relationship Affidavit] form, and sign ... written affidavit” and “then I would call to the office and start questioning the office about whether this – to substantiate the truth about it.” *Id.* at 885. She testified that the Relationship Affidavit was to be completed the “first time only” that a customer came to Respondent pharmacy. *Id.* at 1016. She testified as to what the Relationship Affidavit would “do to alleviate ... [her] concerns that this prescription was not diverted.” *Id.* at 887. She stated that “the major red flag at that time” was “whether patient actually be seen by doctor, not just come to the office and have the prescription ready for them.” *Id.* She continued by stating that “[i]t was not about ... whether this prescription written for Dilaudid or prescription written for – or quantities, it was a concern, but not the main concern.” *Id.* According to Respondent’s Owner and PIC, “[t]he main concern – the problem at the time was the patient going and the doctor’s [sic] are not properly executing the practice that’s reflected in the medical practice law.”¹² *Id.* Her testimony continued: “So we would check, ... would require for the patient has

¹¹ The six Dilaudid 8 mg. prescriptions in GX 19 were written by the same doctor for six different customers in the July-August-November 2012 time period. Specifically, the six Dilaudid 8 mg. prescriptions were for: (1) 174 tablets for a customer from Pompano Beach at a cash price of \$870; (2) 96 tablets for a customer from Fort Lauderdale at a cash price of \$480; (3) 150 tablets for a customer from Miami at a cash price of \$750; (4) 180 tablets for a customer from Pompano Beach at a cash price of \$900; (5) 168 tablets for a customer from Pompano Beach at a cash price of \$840; and (6) 168 tablets for a customer from Coral Springs at a cash price of \$840. Respondent’s Owner and PIC had identified the first prescription for 174 Dilaudid 8 mg. tablets as showing a “major red flag” because it was for a schedule II medication and for 174 tablets. Tr. 881.

¹² Apparently, the “medical practice law” Respondent’s Owner and PIC referenced was the “Ryan Act.” She testified that the purpose of the Relationship Affidavit was to “establish the patient-doctor relationships and the legitimate ill of the patients” in compliance with the “Ryan Act.” Tr. 1015-16. According to Respondent’s Owner and PIC, “by that law is rely if the patient actually has a logical relation with the doctor.” *Id.* at 1016.

She testified further about the “state statute and federal statutes”: “For ... me was most important thing was to go to references of the state statute and federal statutes. So federal statute says, has to be clear relationship to establish the legitimate medical purpose. You rely on the doctors to establish the appropriateness of therapies. It’s not on the pharmacy to establish the appropriateness of pharmacy..., that’s how I understood the law. The pharmacist is just to establish that the prescription was valid – the validity of prescription based that the prescription as a requirement, and the doctor allowed to prescribe, and the doctor actually see the patients. Unless there’s some issues that arise

issues ... [a]nd she has a medical history and there is a logical connection between her and the doctor, there's relationship, it's not just to get a prescription for major narcotics." *Id.* at 887-88. According to Respondent's Owner and PIC, the Relationship Affidavit "resolve[d]" these concerns. *Id.* at 889. She stated, "That form would resolve ... that he's not attempted to fraudulently – to illegally get access to the controlled pain medication." *Id.*; *see also id.* at 1149.

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The Relationship Affidavit was a one-page form with Respondent's name at the top, and name and contact information at the bottom. *See, e.g.,* Respondent Exhibit (hereinafter, RX) 5, at 2. Text on the Relationship Affidavit stated that individuals "who are receiving medications to treat chronic intractable pain are required to be seen and examined by the physician on the same date the prescription for pain has been issued." *Id.* According to the Relationship Affidavit, a customer had to sign it before Respondent would fill a prescription. The Relationship Affidavit stated that:

with that, like, for instance, if the patient is – not that the doctor overly treated or the patient has issues --- or the doctor has issues with the patient, or I feel something suspicious, then I call the doctors. ... Because standards only tell you that you have to actually establish the patient is not coming here for wrong reasons. That's only what the statute says. The statute says if the patient come for wrong reason you don't fill it. If the patient come from appropriate reason, you fill." *Id.* at 1018-19, 1021.

¹³ She also testified that she interacted with Respondent's customers by asking them questions.

I would talk to the patient, ask him about why did he come to my pharmacy? Where did he fill before? What is the reason he doesn't use previous pharmacy? And also, what is the reason for – how long has he been on that medication? And whether he was checked by – and then I would ask him to look at the affidavit form and sign the affidavit form for the patient. ... I have not written those questions out. But they would be the same questions that I would ask to establish ... the history of the patient.

Tr. 882-83, 884. When asked whether she would "essentially" ask every customer the same questions, she responded affirmatively and identified other questions she asked. *Id.* at 884-85. Respondent's Owner and PIC, however, did not explain the purpose of these questions given her testimony that the signed Relationship Affidavits "resolved" the issue of whether customers were attempting to fraudulently or illegally get access to controlled pain medication.

In order for prescriptions to be filled by ... [Respondent] patients are required to sign this affidavit to ensure the following elements exist. By affirming and satisfying the conditions mentioned below ... [Respondent] assumes that the prescription is valid pursuant to a legal Physician Patient Relationship.¹⁴

Id. Notably, Respondent stated its “assumption” that a prescription was valid when customers affirmed and satisfied the Relationship Affidavit’s “conditions mentioned below,” presumably the “elements.” *Id.*

Also of note was the “Warning” on the Relationship Affidavit: “In the event ... [Respondent] has reasons to believe that prescriptions for pain medication have been prescribed and/or received fraudulently we have a legal responsibility to report such activity and individuals to local and federal authorities. These authorities will handle such individual in the manner prescribed by law.” *Id.* Respondent’s Owner and PIC discussed the Relationship Affidavit’s “warning” in her testimony. She stated that “it was actually warning that’s in the case if I find something which would jeopardize or compromise my belief in the validity of the prescription, we have responsibility to report such activity to local and federal police. And the patient knew about it.” Tr. 888. She testified that, “I would say if I ... find something ...— ... like Your Honor giving me the benefit of the doubt, I would give the patient the benefit of the doubt. If I find out that you have a problem, it’s fraudulent, I will report you. So you better not start that process.” *Id.*

In sum, Respondent’s Owner and PIC testified that (1) she assumed the legality of a prescription based on customers’ completion of the Relationship Affidavit, (2) she gave

¹⁴ The referenced “elements” apparently were listed in the last section of the form, which stated: “By signing below, I _____ agree that the following elements of a legal Pain Management Physician-Patient Relationship exist: 1. There is no fraudulent representation to illegally gain access to controlled pain medications 2. There are no multiple doctors “doctor shopping” treating me for pain management 3. A physician has seen and conducted a physical examination 4. A physician has reviewed the patient’s medical history 5. The patient has a medical complaint 6. MRI has been conducted within 24 months of the prescription 7. There is a logical correlation between the following a. Medical Complaint b. Medical History c. Physical Exam d. Prescriptions. _____ Patient Name _____ Date of Birth _____ Signature _____ Date.” RX 5, at 2.

customers “the benefit of the doubt” concerning their completion of the Relationship Affidavit, and (3) she warned customers to “better not start” the process of her “find[ing] out” that a prescription is “fraudulent.” She did not explain why it was reasonable to expect drug seekers to understand what they read, let alone be honest and truthful as they completed and signed the Relationship Affidavit. She also did not explain how giving customers “the benefit of the doubt” was consistent with the requirements of the corresponding responsibility regulation. 21 CFR 1306.04(a).

Fourth, Respondent’s Owner and PIC testified that she “validate[d] that ... it’s a signature ... not rubber signed, ... [the prescription] was actually signed by the physician.” Tr. 892; *see also id.* at 1116-17 (“[T]he issue at the time was not the strength. The issue they were looking for was actually the prescription legitimate ..., it’s not fake Make sure the doctor actually issue it. He didn’t buy it from – on the side, on the street. He didn’t get his prescription from other sources, and actually get it from the doctor.”).

Respondent’s Owner and PIC testified that the concept of “red flags” stood in the way of getting medicine to deserving individuals. She testified that, “by strictly following these red flags, it will prevent legitimate patient from obtaining the medication.” *Id.* at 1108. She testified that she decided not to fill prescriptions for schedule II controlled substances altogether because “following the red flags will prevent me from filling the ... prescriptions for legitimate medical purposes ... and be unfair to the patient.” *Id.*¹⁵

¹⁵ She added, “Except two instances when I had this overstock and the patient was patient of mine for other reasons, we decide to fill. ... And I don’t purchase them [schedule II controlled substances].” Tr. 1108-09.

Before the time she testified to having decided not to fill schedule II prescriptions, Respondent's Owner and PIC testified that her "liability was to prevent the diversion the best that I can, considering it was very, very little guidelines was provided to us at that time. We tried to update it, it was confusing, the red flags was changing." *Id.* at 890. Apparently based on the individual perspective of Respondent's Owner and PIC concerning what pharmacies should do, Respondent designed its own forms "to support the establishment of legitimate medical purpose to fill" prescriptions. *Id.* at 981.¹⁶

¹⁶ See, e.g., RX 6 and RX 10. These exhibits include various items of documentation with respect to fourteen customers which Respondent represented were obtained to determine the validity of the prescriptions. Tr. 824. Each of the exhibits contains a copy of each customer's driver's license, and copies of the Pain Management Physician-Patient Relationship Affidavit for 11 of the customers. There are also copies of printouts from the DEA registration webpage with respect to five of the customers. RX 6, at 3, 18, 35; RX 10, at 6, 12.

There are also copies of a "CII/CIII Rx Verification Form" for four customers in these two exhibits. This was a one-page form on which Respondent would document the date and time of a phone call to a prescriber's office and list the name of the person providing the information. See RX 6, at 6. The form was then used to document "yes" or "no" as to whether: 1) the prescription was written by the prescriber, 2) whether the patient was seen by the prescriber at the prescriber's office, and 3) whether the patient was physically examined by the prescriber, after which the form provided a space for writing the diagnosis. *Id.* The form then included boxes to check whether the prescription was approved or denied, three lines for notes, and a line for the pharmacist to initial. While Respondent's Owner and PIC testified that she used this one-page form "[i]nstead of writing scribbles on the back of the prescription," Tr. 1002, and on each of the four forms, checked "yes" with respect to each question, listed diagnoses codes, and indicated that each prescription was "approve[d]," none of the forms contains additional notes and only two of the forms were initialed by the pharmacist. See RX 6, at 6, 10, 21, 29.

Finally, the exhibits contain copies of E-FORCSE printouts for five of the fourteen patients. See RX 6, at 4, 7, 17, 20, 30. Of note, three E-FORCSE printouts were not obtained until the middle of April 2013, see *id.* at 4, 7, 30, one was obtained on May 13, 2013, see *id.* at 20, and one was obtained on August 23, 2013. *Id.* at 17. As found above, the DI served the Notice of Inspection on Respondent on April 11, 2013.

Respondent's Owner and PIC offered multiple comments about these timing issues: she "would not necessarily print out every time," "the record that I kept in the file obviously was the latest one," and "every time I check, I would check with the PDMP – with the PMP report." *Id.* at 994. When questioned further by the CALJ about the E-FORCSE printout for patient G.A., Respondent's Owner and PIC testified that the State of Florida "would not give us the access" and "for a while I relied on the physician offices to provide me that information. I would call the physician to run the PMP report until I actually were able to get the access myself" *Id.* at 996. Respondent's Owner and PIC stated that she got access to E-FORCSE "sometime during 2013." *Id.* at 997-98.

Respondent's Owner and PIC testified that this information was important to her because it told her "that this patient ... was seen by the same doctor for over ... [a] seven-month period. And so this patient requires therapy. And the doctor was a very local doctor ... [a]nd he was going only to my pharmacy. So [the customer] relied on me to fill her prescription." *Id.* at 986-87. Yet, with respect to patient S.B., her E-FORCSE printout showed that she had filled her controlled substance prescriptions at three different pharmacies as well as through a mail order

I afford Dr. Gordon's statement of the pharmacy's/pharmacist's standard of practice regarding controlled substances controlling weight in this proceeding. I find that the requirements incumbent on pharmacies/pharmacists espoused by Respondent's Owner and PIC are only entitled to credit as I determine what actions Respondent took and Respondent's suitability to be a registrant. Essentially, the views of Respondent's Owner and PIC about a pharmacy's/pharmacist's obligations with respect to dispensing controlled substances reflect an abdication of her legal responsibility to a prescriber with a valid State license and whose DEA registration covered the schedule of the prescribed medication when the customer simply signed the Relationship Affidavit. Significant aspects of the pharmacy's/pharmacist's obligations espoused by Respondent's Owner and PIC were contrary to statute, regulation, and Agency precedent. I categorically reject them.

Allegations that Respondent Failed to Exercise Its Corresponding Responsibility When It Dispensed Controlled Substances Pursuant to Prescriptions Not Issued in the Usual Course of Professional Practice or for a Legitimate Medical Purpose

service, RX 6, at 7, and with respect to patient D.K., his E-FORCSE printout showed that he had filled his prescriptions for both oxycodone and hydromorphone at four pharmacies in addition to Respondent. *Id.* at 20.

While Respondent's Owner and PIC also testified that G.A.'s "established relationship" with the doctor was "one of the thing that you use – one of the tools that you use with – to establish legitimate medical purpose ... [because] you can fairly assume that the patients are being taken [sic] by the physician properly," *id.* at 988-89, Dr. Gordon testified that "[t]he first ... [red flag] that is really bold to me is the doctor. I've worked on other cases, and I've seen this doctor [R.T.] write lots of illegitimate prescriptions." *Id.* at 360-61. Notably, each of the seven prescriptions listed on G.A.'s E-FORCSE printout was written by Dr. R.T., and each prescription was for 150 or 160 dosage units of hydromorphone 8 mg. RX 6, at 4. Dr. R.T. also wrote five of the prescriptions listed on S.B.'s E-FORCSE printout (including all four hydromorphone prescriptions, three of these being for 160 dosage units or more of the 8mg. dosage), *see* RX 6, at 7, and all four hydromorphone prescriptions listed on T.S.'s E-FORCSE printout, each of these being for 150 or more dosage units of the 8 mg. dosage. *Id.* at 30.

Respondent submitted a further exhibit, RX 11, which contained documentation related to other customers. Respondent's Owner & PIC testified that this exhibit was "generated . . . [t]o show in good faith that we are actually conducting best practices. . . . That we document good practice when we fill the patient – we're filling pain medication for sick patient." Tr. 1173-74. The exhibit consist of a photocopy of the driver's licenses of three of the six customers for whom the prescriptions in GX 14 were written; a Relationship Affidavit signed by two of the six customers; and a one page E-FORCSE printout dated months after the corresponding prescriptions in GX 14 were written and filled.

The Show Cause Order alleged that Respondent failed to exercise its corresponding responsibility under 21 CFR 1306.04(a) as evidenced by its having dispensed controlled substances without resolving “red flags of diversion” that were present. The Government alleged seven “red flags of diversion” in the Show Cause Order: prescriptions presented by customers who traveled long distances to Respondent; multiple customers filling prescriptions written by the same prescriber, for the same drugs, in the same quantities, on the same day; multiple customers from the same address coming to Respondent at the same time with prescriptions from the same doctor for the same drug and strength; customers presenting two prescriptions, both for the same immediate release controlled substance, but for different strengths; customers presenting prescriptions with a combination of an opiate and a benzodiazepine or “drug cocktail” popular among drug abusers; customers paying for their prescriptions with cash, when other red flags of diversion were present; and customers presenting new prescriptions for controlled substances when they should not have finished their previous prescription for that drug (“early fills” or “early refills”).

Prescriptions Presented by Customers Who Traveled Long Distances to Respondent

The Government alleged that customers traveling long distances to fill their prescriptions was a “red flag of diversion,” and that Respondent dispensed controlled substances to customers who traveled long round-trip distances, from their homes, to the prescribers, to Respondent, and then back home, without addressing or resolving the distance red flags. To support this allegation, the Government submitted 13 such prescriptions filled by Respondent. *See* GX 8/8a;¹⁷ *see also* Tr. 53 (DI testifying that GX 8 contained fair and accurate copies of the

¹⁷ The materials in GX 8 and GX 8a, 13 prescriptions and corresponding prescription labels, were identical. There were driver’s licenses associated with nine of the 13 prescriptions/prescription labels. GX 8a contained better copies

documents Respondent provided to him). Of the 13 prescriptions in GX 8/8a, nine were for Dilaudid 8mg.¹⁸

The DI testified that he initially identified the prescriptions in GX 8/8a as “problematic” because they showed “[p]eople traveling long distance[s] to the pharmacy.” Tr. 50-51. The parties stipulated to sets of round-trip (by road) miles within the State of Florida. ALJX 20, at 1-2. Those sets of round-trip miles corresponded to miles traveled by customers for whom Respondent filled prescriptions listed in the Show Cause Order and included in GX 8/8a. In sum, the round-trips ranged from 184 miles to 661 miles. I make the following findings:

- One bottle of Buprenorphine Hydrochloride 0.3 mg/mL issued to FW of Deltona by Dr. AF of Hallandale Beach. The parties stipulated that the distance by road from Deltona to Hallandale Beach and back to Deltona is 504 miles.
- 150 tablets of Dilaudid 8 mg. issued to GA of Fort Pierce by Dr. RT of Miami. The parties stipulated that the distance by road from Fort Pierce to Miami to Hallandale Beach and back to Fort Pierce is 261 miles.
- 168 tablets of Dilaudid 8 mg. issued to SB of Fort Pierce by Dr. RT of Miami. The parties stipulated that the distance by road from Fort Pierce to Miami to Hallandale Beach and back to Fort Pierce is 261 miles.
- 150 tablets of Dilaudid 8 mg. issued to CW of Fort Pierce by Dr. RT of Miami. The parties stipulated that the distance by road from Fort Pierce to Miami to Hallandale Beach and back to Fort Pierce is 261 miles.
- One bottle of Buprenorphine Hydrochloride 0.3 mg/mL issued to MW of Hobe Sound by Dr. AF of Hallandale Beach. The parties stipulated that the distance by road from Hobe Sound to Hallandale Beach and back to Hobe Sound is 166 miles.
- 140 tablets of Dilaudid 8 mg. issued to DK of Jensen Beach by Dr. NG of Hallandale Beach. The parties stipulated that the distance by road from Jensen Beach to Hallandale Beach and back to Jensen Beach is 195 miles.

of most of the driver's licenses than GX 8. Tr. 793. Those better copies were added to GX 8 as GX 8a during the hearing on June 11, 2015. *Id.* at 794.

¹⁸ The other four were for buprenorphine (2), Xanax, and testosterone.

- 56 tablets of Dilaudid 8 mg. issued to BS of Port St. Lucie by Dr. ML of Hollywood. The parties stipulated that the distance from Port Saint Lucie to Hollywood to Hallandale Beach and back to Port Saint Lucie is 201 miles.
- 150 tablets of Dilaudid 8 mg. issued to TS of Sebastian by Dr. RT of Miami. The parties stipulated that the distance from Sebastian to Miami to Hallandale Beach and back to Sebastian is 318 miles.
- One bottle of testosterone cypionate 210 mg/mL issued to RV of Sebring by Dr. AF of Hallandale Beach. The parties stipulated that the distance by road from Sebring to Hallandale Beach and back to Sebring is 312 miles.
- 112 tablets of Dilaudid 8 mg. issued to BR of St. Pete Beach by Dr. DJ of Deerfield Beach. The parties stipulated that the distance by road from Saint Pete Beach to Deerfield Beach to Hallandale Beach and back to Saint Pete Beach is 538 miles.
- 112 tablets of Dilaudid 8 mg. issued to WP of Stuart by Dr. GF of Pembroke Park. The parties stipulated that the distance by road from Stuart to Pembroke Park to Hallandale Beach and back to Stuart is 184 miles.

GX 8/8a.

Dr. Gordon testified that the long distances the customers traveled in connection with obtaining and filling all of the prescriptions in GX 8/8a were red flags. Tr. 353-62, 365, 368, 370, 372, 374-77, 380-82, 384-85, 387-92. She explained: “Pharmacies that dispense prescriptions that are not for legitimate medical purpose, they have a tendency to develop a reputation. And then the other drug seekers find out about it, and they’ll go to any distance to get what they need for their – to satisfy their addiction.” *Id.* at 355.

For 12 of the 13 prescriptions, Dr. Gordon was asked to look for notations on the prescriptions evidencing that the filling pharmacist had taken steps to attempt to resolve the prescriptions’ red flags, or she looked for notations herself. She found none. *Id.* at 356, 364, 369, 371, 373, 374, 377, 381-82, 384, 387-88, 389-90, 391. On cross examination, Dr. Gordon testified to the absence of documentation on the other prescription. *Id.* at 494. Dr. Gordon was asked whether the distance red flags on 12 of the prescriptions were resolvable. She testified

they were not. *Id.* at 355, 367, 369, 371, 373, 374, 377-78, 382, 384, 388, 390, 391. She was not asked about the resolvability of the distance red flag on the other prescription, but said that its red flag had not been “resolved.” *Id.* at 364. Of that prescription, she also stated: “That’s a very long distance [261 miles from Fort Pierce to Miami to Hallandale Beach to Fort Pierce] for somebody that has pain to be driving – sitting in a car for that long to obtain Dilaudid 8, which is the highest milligrams it comes in.” *Id.* at 361.

In sum, Dr. Gordon concluded that none of the 13 prescriptions was legitimate and that the pharmacist who filled the prescriptions had not exercised her corresponding responsibility to make sure the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* at 357, 364-65, 367-78, 370, 371, 373, 375, 378, 382, 385, 388, 390, 391-92.

Mr. Fisher’s testimony about whether distance was a red flag was inconsistent. At one point, Mr. Fisher testified that the prescriptions included in GX 8 evidenced distance red flags, and that he believed they could have been resolved. *Id.* at 596-97. “Usually,” he stated, “a prescription is going to be filled close to where the physician is or close to where the person lives.” *Id.* at 597; *see also id.* at 601 (Mr. Fisher’s testimony that Fort Pierce is a “distance from the area.”). At another point, however, Mr. Fisher appeared to testify that distance was a red flag only when Respondent was asked to fill prescriptions for intrastate customers, as opposed to out-of-state customers, even though out-of-state customers would be located further from Respondent than intrastate customers. *Id.* at 745. The CALJ sought clarification, asking: “[I]f a person was a long distance but they were in Florida, that would be a red flag. But if a person was living a long distance ... in Georgia, that’s not a red flag? ... So what’s your final answer; that it is a distance red flag or it’s not.” *Id.* at 745-46. Mr. Fisher responded: “It’s a distance red

flag, which is resolvable.”¹⁹ *Id.* at 746; *see also id.* at 754. Thus, Mr. Fisher eventually agreed with the testimony of the Government’s expert that customers who traveled long distances to fill controlled substance prescriptions were red flags.

Respondent’s Owner and PIC admitted that Respondent filled the prescriptions in GX 8/8a. *Id.* at 979. She testified that it was not a red flag “by itself” for customers within the State of Florida to come over 100 miles from their homes to fill a controlled substance prescription at her pharmacy. *Id.* at 1028; *see also id.* at 1021-22 (In 2012 and 2013, “the fact that a patient traveled a long distance ... was not a major red flag, no.” There were “other red flags that I was concentrating on.”).

Respondent submitted CII/CIII Rx Verification Forms for four of the 13 prescriptions in GX 8/8a.²⁰ RX 6, at 6, 10, 21, and 29. According to Respondent’s Owner and PIC, these four forms were part of Respondent’s “patient files,” the “documents – prescriptions, prescription labels, and corresponding documents which assisted me to resolve the red flags made by ... [Respondent] and kept in the regular course of business.” Tr. 824-25. She asserted that the CII/CIII Rx Verification Form was a “step ahead,” and “above and beyond” the “general practice of most of the pharmacies in the State of Florida.” *Id.* at 1001. She further testified that “[i]nstead of writing scribbles on the back of the prescription, ... you have, more or less, here on form.” *Id.* at 1002.

While the forms contained diagnosis codes, only two of the forms were initialed by the pharmacist, and none of the forms contained any notes explaining how Respondent’s pharmacist

¹⁹ When Respondent’s counsel argued that Mr. Fisher “did not testify in all other cases that the distance was a factor and testified in this case -- ... I’m talking about as out-of-state prescriptions, that distance is not a factor” and that “[t]he method of delivery is completely different ... [s]o those two are not even analogous,” the CALJ responded: “The record will stand as it is.” Tr. 746-47.

²⁰ The CII/CIII Rx Verification Forms concern the prescriptions in GX 8/8a written for SB, CW, DK, and TS.

resolved whatever prompted her to call the prescriber even though the form contained three lines for this purpose. RX 6, at 6, 10, 21, 29. Regarding the incompletions, Respondent's Owner and PIC testified both that: (1) "sometime we get busy, I know the office is called" and "I did look at the paper, because I would not fill the prescription unless I look at the paper;" and (2) "[i]f it's a routine patient who comes – who's been already established by me, ... same prescription that's filled before, we would just – probably would be a little bit more routine in the call." *Id.* at 1004, 1005-06 (respectively). This testimony of Respondent's Owner and PIC was inconsistent with her testimony that "When all the schedule II prescriptions – I would talk to doctor on each prescription." *Id.* at 1116.

Respondent's Owner and PIC stated that she did not document all her conversations with doctors because "it's my kind of internal – I did it to make a proper, sound clinical judgment whether this patient appropriate to get ... these filled prescriptions." *Id.* at 1010. Notably, she stated that, "I do accept responsibility for that and I don't do it any more. Now I document every little thing that it's concerned to the conversation and the dispensing of controlled substances." *Id.* She also said that, "again, like I said, I accept responsibility for that and I improve my practice now. I do document everything that's possible to. However, like I said, this happens all the time." *Id.* at 1011. She added that "we cannot have 100 percent even if it's red flag. ... You try to do the best that you can, but sometimes it happens." *Id.* at 1012.

The CALJ noted that "it seems to me that on the form that you're giving me, the place that that should have been noted is down at the bottom where it says 'notes,' and also the pharmacist's initials if you had made the call."²¹ *Id.* at 1013. Respondent's Owner and PIC, correlating the exercise of her corresponding responsibility with her practice in school of "taking

²¹ Two of the forms' "Pharmacist's Initials" sections were completed. No form's "Notes" section contained a note.

very little notes,” admitted that “I do have a tendency not to take too many notes” and confirmed that “I should learn how to take better notes.” *Id.* at 1014. She said that she “took remedial steps for it” by “hir[ing] new person who actually specifically look if I leaving the notes ... and everything is properly taken right now.” *Id.* Further, Respondent’s Owner and PIC admitted that red flags identified from E-FORCSE were not noted, nor was their resolution documented, on the corresponding CII/CIII Rx Verification Form. *Id.* at 1010.

Based on the testimony of both Dr. Gordon and Mr. Fisher, I reject the testimony of Respondent’s Owner and PIC that “the fact that a patient traveled a long distance ... was not a major red flag.” I further find not credible the testimony of Respondent’s Owner and PIC that she did not consider a controlled substance prescription presented by a customer who travelled a long distance to be a red flag and conclude the exact opposite to be the case.

I find that each of the prescriptions in GX 8/8a raised at least one red flag that required resolution in that customers traveled long distances to obtain controlled substances, including schedule II controlled substances that even Respondent’s Owner and PIC admitted were “highly risky” and subject to “a lot of diversion.” *Id.* at 1129, 1116, respectively. I find that Respondent admitted filling the prescriptions in GX 8/8a. Based on the testimony of both Dr. Gordon and Mr. Fisher, I find that, at a minimum, the distances the patients traveled to present the prescriptions in GX 8/8a required Respondent to resolve the distance red flags before dispensing controlled substances. I further find that Respondent did not address or resolve the red flags before filling the prescriptions in GX 8/8a.

Multiple Customers Filling Prescriptions Written by the Same Prescriber, for the Same Drugs, in the Same Quantities, on the Same Day

The Government alleged that prescriptions written by the same prescriber, for the same drugs, in the same quantities, and on the same day was a “red flag of diversion,” and that Respondent filled such prescriptions without resolving that red flag. As support for this allegation, the Government submitted five prescriptions that were written by the same doctor (Dr. A.F.) on the same day (June 27, 2012), and for the same strength of the same medication (testosterone cypionate). *See* GX 10; *see also* Tr. 394 (testimony of Dr. Gordon), Tr. 67 (DI testifying that GX 10 contained fair and accurate copies of documents he obtained from Respondent on April 11, 2013), and Tr. 68. Respondent filled them all on June 28, 2012, between 11:24 a.m. and 12:56 p.m., a period of about an hour and a half. GX 10.

In Dr. Gordon’s view, “[t]hese prescriptions present a big red flag.” Tr. 394. “[I]t’s odd,” she testified, “that a compounded script would be made exactly the same for each of these patients, which means there’s not individualized therapy.” *Id.* The lack of individualized treatment meant to Dr. Gordon that “the prescriptions were not written for a legitimate medical purpose.” *Id.* at 396. She testified that she did not see any notations on the prescriptions evidencing that a pharmacist attempted to address the red flags. *Id.*; *see also* R.D., at 49 (Respondent’s Owner and PIC “conceded that the paperwork furnished to the DIs at the April 11th Inspection did not memorialize any attempts to resolve this red flag and agreed that she did not have any paperwork documenting her identification or resolution of the issue.”). Dr. Gordon’s testimony was that this red flag was not resolvable. Tr. 396. She testified that the pharmacist who filled the prescriptions did not exercise her corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* at 396-97.

At first, the “only comment” that Mr. Fisher had about the prescriptions in GX 10 was that “there doesn’t seem to be a quantity that’s identifiable.” *Id.* at 618. When asked specifically about the fact that the prescriptions came from the same doctor and for the same drug, Mr. Fisher testified that, “[i]f the doctor is specializing in men’s health ..., he could have multiple patients on the same regimen of drugs.” *Id.* at 619. On cross examination, however, Mr. Fisher admitted that the five prescriptions were an example of “pattern prescribing,” or when “a doctor ... writes the same thing for every single patient that comes in.” *Id.* at 769. Mr. Fisher then testified that pattern prescribing was a “red flag for diversion.” *Id.*

Respondent’s Owner and PIC testified that the prescriptions raised a red flag because they were for a “schedule [sic] medication, testosterone.” ²² *Id.* at 1084. She testified that she resolved this red flag by asking the prescribing doctor “if she knows the purpose of this ... treatment, and if the patient are ... taking it for an appropriate use.” *Id.*

Respondent’s Owner and PIC also testified that these five prescriptions raised red flags because “[t]hey came on the same day with the same medication at the same ... dose ... [a]nd the same doctor.” *Id.* at 1092. At this juncture, her testimony about how she resolved the red flags was that she spoke with the doctor. *Id.* at 1092-93. She testified that, “The reason ... they come on the same day, because the doctor designated that day to see patients who need hormonal replacement. ... [I]t helps her to keep the records straight [T]hey start out on the same dose. This way it’s easier to achieve the day to day concentration of the dose.” *Id.* In response to

²² Respondent’s Owner and PIC testified that the red flag for the testosterone prescription on page 3 of GX 10 was the customer’s age, 27 years old. Tr. 1086. She stated that she spoke with the doctor about this prescription and the “doctor assured me that this patient has low testosterone and he needs because he feels very tired and he’s not going to use it for athletic purposes. He was not an athlete.” *Id.*

whether she had any notes “anywhere” documenting her conversation with the physician, Respondent’s Owner and PIC replied, “Not here, no.” *Id.* at 1094.

Based on all of the evidence in the record, I find that Respondent filled prescriptions that raised the red flag of multiple customers presenting prescriptions written by the same prescriber on the same day for the same medication in the same quantity. I further find that, even if these red flags were resolvable, there was no credible evidence that Respondent addressed or resolved them before filling the prescriptions. I cannot, and do not, place any weight on the testimony of Respondent’s Owner and PIC that she resolved these red flags because she produced no documentary evidence to support her claim that she attempted to and, in fact, did resolve them before filling the prescriptions.

Multiple Customers from the Same Address Coming to Respondent at the Same Time with Prescriptions from the Same Doctor for the Same Drug and Strength

The Government alleged that multiple customers from the same address coming to Respondent at the same time with prescriptions written by the same doctor for the same drug and strength was a “red flag of diversion,” and that Respondent filled such prescriptions without resolving that red flag. To support this allegation, the Government submitted two prescriptions for Dilaudid 8 mg. that Respondent filled within five minutes of each other. *See* GX 11. The prescriptions were written by the same doctor on the same day with the same use directions to two individuals with the same last name and street address in Hollywood, Florida. *See* Tr. 397-98; *see also id.* at 70 (DI testifying that GX 11 consisted of true and accurate copies of prescriptions and labels he took from Respondent on April 11, 2013) and *id.* at 71 (DI testifying that the prescriptions in GX 11 were for two customers living at the same address, who saw the same doctor, were prescribed the exact same drug and strength, and then took those prescriptions

to Respondent at the same time). The difference between the two prescriptions was that one was for 80 tablets and the other was for 85 tablets. *Id.* at 397; *see also* GX 11, at 1, 3.

In Dr. Gordon's opinion, these prescriptions raised multiple red flags that were not resolvable. Tr. 397-98. She testified that: "This to me is what's called rubber-stamping from a physician, and is not individualized therapy. ... It's unusual that two patients that live at the same address would receive the same exact therapy. There's always an exception to the rule, but this is common in the drug-seeking community" *Id.* Dr. Gordon also testified that there were no notations on the prescriptions addressing the red flags. *Id.* at 398. Her opinion was that the prescriptions were not legitimate and that the pharmacist who filled the prescriptions had not exercised her corresponding responsibility to ensure the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* at 398-99.

Mr. Fisher agreed with Dr. Gordon that the prescriptions raised red flags. He testified that the "same address for two different people" and the "same drug" were red flags associated with these prescriptions. *Id.* at 620. He considered it "very possible" that the prescriptions were for husband and wife who had a reason for going to the same doctor at the same time. *Id.* He suggested that "[s]peaking to the physician would be the easiest way" to resolve those red flags. *Id.* On cross-examination, Mr. Fisher agreed that a pharmacist's "due diligence ... [and] the standard way to try to prevent diversion of drugs" required the pharmacist to "check the other things available ... [l]ike the E-FORCSE system, ... the doctor's license number, and all that. The routine things you do with a Schedule II prescription." *Id.* at 771. He also contradicted his earlier testimony when he admitted that, in this situation, a "simple phone call to the doctor" might not achieve the level of satisfaction concerning the prescriptions' legitimacy the

“pharmacist has to get ... before they can fill the prescription,” because “the doctor, himself, may not have issued ... [the prescriptions] for legitimate medical purpose[s] in the course of his professional practice.” *Id.* at 771-72.

According to Respondent’s Owner and PIC, the fact that the prescriptions were written by the same doctor, for the same drug and dosage, for individuals living at the same address who had the same last name and presented the prescriptions on the same day did not raise a red flag. *Id.* at 1097-98. She testified that she “would treat ... [the prescriptions] the same way I treat every other schedule II medication.” *Id.* at 1098. She also stated that she filled the prescriptions because, at the time, “I thought the circumstances of the prescriptions were understandable.” *Id.* at 1103-04. She then stated that, as of 2015, she would not fill them “[b]ecause the DEA have restriction on filling those prescriptions[,] ... [n]ot because the patient are not legitimate and not because of doctor not legitimate or not legitimate medical purpose. Only because DEA said do not fill those prescriptions.” *Id.* at 1104. When asked if someone at DEA told her not to fill schedule II prescriptions, Respondent’s Owner and PIC responded: “Obviously, if they bring me that case, that what they saying to me. They will try to take – intend to revoke my license for filling those prescriptions. ... The[y] didn’t tell me – not until they come with this order to show cause.” *Id.* at 1104-05.

Based on all of the evidence in the record, I find that the prescriptions in GX 11 raised red flags because customers with the same last name and street address presented them, and they were written on the same day by the same doctor for the same drug and strength. Further, I find that Respondent admitted filling the prescriptions even though these red flags were not resolvable, according to Dr. Gordon’s testimony. I find that, even if these red flags were resolvable, there was no credible evidence in the record that Respondent addressed or resolved

them before it filled the prescriptions. Respondent's Owner and PIC offered no evidence to substantiate her testimony that the circumstances of the prescriptions were "understandable" and did not raise red flags. I afford her testimony no weight.

Customers Presenting Two Prescriptions, Both for the Same Immediate Release Controlled Substance, but for Different Strengths

The Government alleged that a "red flag of diversion" was raised when customers presented two prescriptions for the same immediate release controlled substance, but for different strengths, and that Respondent filled such prescriptions without addressing or resolving the red flag. As support for this allegation, the Government submitted four such prescriptions filled by Respondent. *See* GX 12. The four prescriptions consisted of two prescriptions each for Dilaudid 8 mg. and Dilaudid 4 mg. written for two different people. Tr. 399, 405-06; *see also id.* at 72 (DI testifying that GX 12 contained true and accurate copies of documents he took from Respondent on April 11, 2013) and *id.* at 73 (DI testifying that the prescriptions in GX 12 belonged to two patients for the same immediate-release drugs and strengths). Dr. Gordon testified that the prescriptions raised red flags. *Id.* at 399-400, 403-04. The first red flag she identified was that the two prescriptions were written for the same immediate release controlled substance, but for different strengths. *Id.* at 399. The second red flag she identified was the diagnosis of "lumbar radiculopathy." *Id.* at 400.

Dr. Gordon explained that giving one person two prescriptions for two immediate release opioids was not necessary because the Dilaudid 8 mg. could be broken in half to get a 4-milligram dose. *Id.* at 399. She pointed out that there was no long-acting medication accompanying the prescriptions in GX 12 and that "[t]wo immediate-release opioids is ... a common red flag for diverted prescriptions." *Id.*; *see also id.* at 399-400. She explained: "In pain management ... you start out with a short-acting. Then based on the amount of short-acting,

you prescribe a long-acting, because if you were in pain, I wouldn't want you to have to take something every four hours. ... So what we do is we recommend ... a long-acting ... with a break-through." *Id.* at 401. Her testimony further explained that "it looks like the practitioner was trying to say that you could only take Dilaudid, 4 milligrams, one, three times a day ... [but] [i]t won't last eight hours. So that's the first red flag." *Id.* at 403. She continued, asking rhetorically "why would you take a higher dose of a break-through? It doesn't make any sense." *Id.* Drawing from her experience, she testified that "it would have made more sense for him to schedule the eight[;] ... it's usually the same dose for break-through." *Id.*

Dr. Gordon also testified that the diagnosis of "lumbar radiculopathy" was "a red flag to take pause for any reasonable pharmacist to make sure the prescriptions are legit." *Id.* at 400. *See* GX 12, at 1-2. She explained that, "on prescriptions that are not legit, that's the pattern I've seen – lumbago is big on illegitimate prescriptions – and most of my colleagues as well." Tr. 404.

When asked if she would "reach out to the prescriber" if she "were in a retail pharmacy and ... saw a prescription like this coming in with two short-actings," Dr. Gordon responded "[n]o. ... I would give the prescriptions back to the patron." *Id.* at 402. She stated that the red flags raised by the prescriptions were not resolvable. *Id.* at 405, 406. Dr. Gordon testified that there were no notations on the prescriptions addressing the red flags, and gave her opinion that the prescriptions were not legitimate and that the pharmacist who filled the prescriptions did not exercise her corresponding responsibility to ensure the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* at 404-05, 406-07; *see* GX 12, at 1-8.

Mr. Fisher agreed that “two prescriptions written for the same person for the same drug but different strengths” was a red flag. Tr. 620-21. He testified that he would speak to the doctor to resolve it because it’s “[c]ommonly done” to “try[] to achieve a certain therapeutic level by combining the two doses ... [because] [t]he 8 milligrams is not enough for the patient, so they do 12.” *Id.* at 621. Mr. Fisher testified that a consistent therapeutic level would be achieved if the medication were taken as directed during a 24-hour cycle. *See id.* at 624. He stated that “three times a day, you’re going to take it probably You’re not taking it in the middle of the night. You’re probably going to take it morning, noontime, and suppertime. And then he goes to work and he needs something stronger and he takes the stronger dose. ... It is common.” *Id.* at 624-25.

Respondent’s Owner and PIC testified that the only red flag she associated with the prescriptions in GX 12 was that they were for schedule II controlled substances. *Id.* at 1115, 1129. When asked if “the fact that there was two different strengths of the same medication, issued to the same patient on the same day by the same doctor ... constitutes a red flag,” Respondent’s Owner and PIC replied in the negative “because there is a logical explanation to it.” *Id.* at 1115. “That’s done ... to achieve certain dosage variance,” she stated. *Id.* After further questioning on the subject, Respondent’s Owner and PIC stated that she “spoke with the doctor about it and doctor approved the dose.” *Id.* at 1121; *see also id.* at 1132-33. She added that the doctor was “still practicing ... [a]nd the patient tells me that’s how he benefits the most.” *Id.* at 1121. She testified similarly regarding the prescriber of the other prescriptions in GX 12. *Id.* at 1126.

When asked whether she had, for these prescriptions, “the same documentation that you’ve shown before ... [l]ike ... the patient agreement and the PMP report and a note that

somebody checked with the doctor,” Respondent’s Owner and PIC answered affirmatively. *Id.* at 1121-22. She admitted that she had not, however, provided the same documentation. Instead, she stated that the existence of the “approved” stamp and “my personal stamp with my signature on it” meant that “I spoke with the doctors. ... And documents were obviously generated when he comes – visiting the pharmacy, otherwise I would not dispense it.” *Id.* at 1122. When asked, however, whether “[e]very time you see that stamp, you spoke with the doctor,” Respondent’s Owner and PIC declined to respond in the affirmative. *Id.* at 1136-37. She stated, “I have to go each prescription by – let’s go one-by-one each prescription, I tell you each one I spoke with.” *Id.* at 1137. She testified that, “I called – as far as I remember, on each prescription, every time it’s presented to me, I called the office. Not necessarily I would speak every time with the doctor. ... But the practice was at the pharmacy, we verify every prescription.” *Id.* at 1138. During cross-examination, Respondent’s Owner and PIC testified that the absence of the stamps would not mean that a prescription was not valid “[b]ecause, again, there’s sometimes human distractions and errors, some paper can be missed. ... Again, I was not obligated by either the State or law to stamp those prescriptions.” *Id.* at 1226. She testified that, “I did my best attempt to make sure there’s no fraudulent prescription I fill there. Or there’s no valid DEA numbers or there’s, like, no major violation or diversion with the prescriptions.” *Id.* at 1227.

Respondent’s Owner and PIC was satisfied, she testified, when she filled the prescriptions in GX 12 that each “prescription was filled for medical purpose within the scope of a physician practice.” *Id.* at 1139.

Based on all of the evidence in the record, I find that Respondent, without addressing or resolving the red flags, filled prescriptions that raised the red flag of customers presenting two prescriptions for the same immediate release controlled substance but for different strengths.

The testimony of Respondent's Owner and PIC, including her testimony that she filled each prescription in GX 12 only after being satisfied they were for a medical purpose within the scope of a physician practice, was not credible. First, it directly conflicted with her original testimony denying that the circumstances raised a red flag and, second, she did not produce any documentary evidence to corroborate her statements.

Customers Presenting Prescriptions with a Combination of an Opiate and a Benzodiazepine or "Drug Cocktail" Popular with Drug Abusers

The Government alleged that prescriptions with a combination of an opiate and a benzodiazepine are "drug cocktails" popular with drug abusers and, therefore, raise "red flags of diversion," and that Respondent filled such prescriptions without addressing or resolving those red flags. To support this allegation, the Government submitted seven sets of prescriptions (a total of 14 prescriptions) that Respondent filled and dispensed to its customers containing an opiate and a benzodiazepine. *Id.* at 407, 412, 414-15, 417, 421, 422-23, 424; *see* GX 13; *see also* Tr. 73-74 (DI testifying that GX 13 consisted of true and accurate copies of documents he took from Respondent during the unannounced inspection) and Tr. 74-75 (DI testifying that the prescriptions in GX 13 were for a common drug cocktail of a narcotic pain reliever and a benzodiazepine, both at their highest strengths).

<u>Drug</u>	<u>No. of tablets</u>	<u>Date Written</u>	<u>Customer's Initials</u>
Dilaudid 8 mg.	116	11/20/12	DC
Xanax 2 mg.	43	11/20/12	DC
Dilaudid 8 mg.	140	12/27/12	DC
Xanax 2 mg.	42	12/27/12	DC
Dilaudid 8 mg.	140	1/24/13	DC
Xanax 2 mg.	42	1/24/13	DC
Dilaudid 8 mg.	162	10/26/12	LF
clonazepam 2 mg.	30	10/26/12	LF

Dilaudid 8 mg.	162	12/21/12	LF
clonazepam 2 mg.	30	12/21/12	LF
Dilaudid 8 mg.	70	10/12/12	BK
Valium 10 mg.	42	10/12/12	BK
Dilaudid 8 mg.	35	11/9/12	BK
Valium 10 mg.	42	11/9/12	BK

According to Dr. Gordon, these seven pairings of prescriptions were considered “cocktail medications,” red flags, because they were multiple drugs that suppressed the central nervous system and, when taken together, could give euphoria. Tr. 408, 412, 414-15 (maximum strength of Dilaudid and Xanax), 417, 421, 422 (highest Valium dose available), 424 (highest doses available), 546, 547. She elaborated on what makes a drug cocktail by testifying that it consisted of “drugs that cause you to have a high.” *Id.* at 547. “So it could be an opioid, it could be an upper and a downer,” she stated. *Id.* She explained that the “person could be taking the drugs to get a high during the day and then a low at night. ... “[I]t’s not being used for what it’s intended to be used for.”²³ *Id.* She explained that “these two drugs are very highly sought after on the street.” *Id.* at 409. In her opinion, the drug pairings were “surrounded by diversion.”²⁴ *Id.* at 410; *see also id.* at 413-14.

Dr. Gordon addressed whether a muscle relaxant had to be present to constitute a drug cocktail. She stated that, “Cocktail medications usually ... are a combination of an opioid plus or minus a benzo plus or minus a muscle relaxant.” *Id.* at 408. Then she explained: “But what

²³ Dr. Gordon testified that the prescriptions would not raise a red flag for her if they were written by a “Hospice doctor[or] oncologist.” Tr. 545.

²⁴ Dr. Gordon identified additional red flags regarding the prescriptions in GX 13: first, the prescriptions on pages 13 and 15 were written for a male (LF) living in Davie and traveling a long distance to Miami to see an OB/GYN (Dr. R.T.); second, the diagnosis written on the prescription on page 13 was lumbago, a common diagnosis that doctors used on diverted prescriptions; and third, the repeat customer (LF) for the prescriptions on pages 13 through 19 written by Dr. R.T. was receiving the same cocktail medications with no long-acting medication present. Tr. 16-17, 418, 420-21.

I've seen ... lately is the doctors have stopped the Soma, and they are just doing, now, high doses of Dilaudid, high doses of benzos. It used to be Oxys. Now they've switched to hydromorphone. So you see ... the flags change." *Id.* She added that, "I see the physicians and drug diverters trying to eliminate one of the components of the cocktail to try to get away with diverted drugs." *Id.* at 538.

Dr. Gordon testified that she saw no notations by the pharmacist on the prescriptions attempting to resolve the red flags and, in her opinion, the "cocktail" red flags were not resolvable. *Id.* at 411, 414, 416, 418, 421, 423, 424-25. She specifically testified that the prescriptions were not legitimate and that the pharmacist who filled the prescription pairings did not exercise her corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.* at 411-12, 414, 416, 418-19, 421-22, 423, 425.

Mr. Fisher stated that he did not consider the drugs in the prescriptions in GX 13 to be cocktails. *Id.* at 629, 631, 632, 633. He elaborated: "To me a cocktail is when you have a combination of three drugs: alprazolam, oxycodone or hydrocodone, and carisoprodol. This to me looks like a simple case of a patient getting pain medication and some Xanax for anxiety." *Id.* 629; *see also id.* at 630 ("[I]n everything I have read and have seen and talked to and have heard at meetings, it's a combination of the three drugs represents the cocktail."). Mr. Fisher agreed that "[a]s things have changed, yes, other drugs have been added like the hydromorphone that's come into play." *Id.* at 629-30. He testified that what makes a cocktail is "more the street value of the drugs." *Id.* at 630.

On cross-examination, Mr. Fisher reaffirmed his opinion that a cocktail involves an opioid, a benzodiazepine, and carisoprodol. *Id.* at 772. He acknowledged that a customer could

obtain the opioid and the benzodiazepine from one pharmacy and the carisoprodol from a second pharmacy. *Id.* at 772-73. He agreed that “the only way to check for that would be through use of ... E-FORCSE.” *Id.* at 773. Mr. Fisher also agreed that Respondent, “not having access to query E-FORCSE, would not be able to ... check for that, those instances of drug seekers using other pharmacies or doctors to obtain a third drug that could be used in this cocktail.” *Id.* On re-direct, Mr. Fisher stated that, beside using E-FORCSE, other ways to resolve any red flags associated with GX 13 were “[c]all the physician, discuss their treatment modality for the patient, [c]heck the patient’s profile if you maintain one[,] ... [and] [i]f you have a computer system you could check and see if there’s a history of the patient getting other prescriptions filled.” *Id.* at 779.

Respondent’s Owner and PIC did not agree that the prescriptions in GX 13 constituted a drug cocktail because, in her view, a drug cocktail had four components: two opioids, carisoprodol, and a benzodiazepine. *Id.* at 1142. “It’s multiple – it’s two – for instance, oxycodone and Vicodin together with Soma and benzodiazepine,” she stated. *Id.* According to Respondent’s Owner and PIC, she “didn’t fill those prescriptions for the Soma, benzodiazepine, carisoprodol,” and she did not recall ever filling a benzodiazepine, Soma, and opiate combination for any patients. *Id.* at 1144, 1145.

Respondent produced an exhibit containing various documents concerning the three customers who asked Respondent to fill the prescriptions in GX 13. RX 10. According to the testimony of Respondent’s Owner and PIC, Respondent compiled or generated the documents in RX 10 “at that time in 2013” because “[w]e tried to implement as much possible steps and follow them through as much as possible to make sure that ... steps are taken ... that’s preventing. ... Also, ... that’s why ... when the patient knows the pharmacy takes extra steps

and scrutinize the prescriptions, people who has non-valid prescription not come to me.” Tr. 1157-58.

Page 2 of RX 10 was the Relationship Affidavit signed by DC, the same DC associated with six prescriptions in GX 13 (pages 1 through 12). *See id. at 1145-46*. Similarly, the Relationship Affidavit on page 5 of RX 10 was signed by LF, the same LF associated with pages 13 through 20 of GX 13.²⁵ *See id. at 1148-49*.

Respondent also provided registration validation pages purportedly printed from DEA’s website. According to Respondent’s Owner and PIC, the DEA registration validation website satisfied her that, on the day she filled LF’s Dilaudid and clonazepam prescriptions, the prescribing physician was “allowed to prescribe the pain medications.” *Id. at 1149; see RX 10, at 6; GX 13, at 17, 19*. Likewise, according to Respondent’s Owner and PIC, the DEA registration validation website showed her that the physician who prescribed prescriptions for BK “was actually scheduled to prescribe schedule II narcotics.” Tr. 1156; *see RX 10, at 12; GX 13, at 21-27*.

Respondent also submitted a hand-written note on a piece of prescription paper belonging to the doctor who issued Dilaudid and Valium prescriptions for BK. *See RX 10, at 10; GX 13, at 21, 23, 25, and 27*. The note was not addressed to anyone. It showed BK’s name in the “patient” space, and an age, partial address, and date in the lines of the prescription paper calling for that information. It did not include a diagnosis. The note contained a signature which, according to Respondent’s Owner and PIC, was the prescribing doctor’s signature. Tr. 1152. The note stated that “the patient cannot tolerate for long periods of kneel, more than 20 minutes of sitting or standing.” *Id.* Significantly, the date on the note (August 9, 2011) was more than a year and two

²⁵ LF did not complete the Relationship Affidavit in full.

months before the date on the earliest prescription issued to BK and included in GX 13 as filled by Respondent (October 12, 2012). *Compare* RX 10, at 10 with GX 13, at 21. Yet, Respondent's Owner and PIC testified that: "Because I've been calling to the doctor and asking about this patient few times ...[,] [w]e make sure the doctor just write a note."²⁶ Tr. 1152. She continued, stating, "[T]his patient has such a difficult time to fill his prescriptions. ... This patient could not fill prescription anywhere, and then he come to me." *Id.* She did not explain how this note led her to conclude that the prescriptions issued to BK were legitimate.

Respondent also submitted a "Verification of legitimate purpose of prescribing CII-CV medications To establish legitimate Physician-patient relationship." RX 10, at 11. It purported to be signed by BK, the individual for whom the Dilaudid and Valium prescriptions on pages 21, 23, 25, and 27 of GX 13 were written. This one-page sheet had space for the customer's name, signature, birth date, and appointment date, for the physician's name and address, and for "yes" or "no" responses to whether the physician or "qualified medical professional" conducted a medical examination, took a blood sample, and had an "MRI on file." *Id.*

I find, based on Dr. Gordon's testimony and consistent with my credibility determinations giving Dr. Gordon's testimony regarding the practice of pharmacy in Florida more weight than any other witness's testimony in these proceedings, that the prescriptions in GX 13 were "drug cocktails" popular with drug abusers. Based on all of the evidence in the record, I find that Respondent filled prescriptions without having resolved the red flags of customers presenting prescriptions with a combination of an opiate and a benzodiazepine which is a common "drug cocktail" popular with drug abusers.

²⁶ She did not address the timing of how Respondent could have "made sure" the doctor wrote a note more than a year before Respondent filled the earliest prescription in the record.

Customers Paying for Their Prescriptions with Cash, when Other Red Flags of Diversion Were Present

The Government alleged that customers paying cash for their prescriptions when other red flags of diversion were present was a “red flag of diversion,” and that Respondent dispensed controlled substances to customers without resolving the red flags those prescriptions presented. As support for this allegation, the Government listed 50 prescriptions in the Show Cause Order. ALJX 1, at 5. No testimony disputed the allegations that Respondent filled the 50 prescriptions and that those prescriptions were purchased with cash. I reviewed those 50 prescriptions. Thirty-two of them were for Dilaudid 8 mg. GX 8, 11, 12, 13, 14.

<u>Drug</u>	<u>No. of tablets</u>	<u>Date Written</u>	<u>Cash Paid</u>	<u>Customer</u>
Dilaudid 8 mg.	150	12/10/12	\$750.00	GA
Dilaudid 8 mg.	168	11/20/12	\$840.00	SB
Dilaudid 8 mg.	150	12/19/12	\$750.00	CW
Dilaudid 8 mg.	56	7/9/12	\$280.00	JS
Dilaudid 8 mg.	140	1/21/13	\$840.00	DK
Dilaudid 8 mg.	56	9/6/12	\$40.00	BS
Dilaudid 8 mg.	150	12/28/12	\$750.00	TS
Dilaudid 8 mg.	112	4/26/12	\$560.00	BR
Dilaudid 8 mg.	112	11/14/12	\$560.00	WP
Dilaudid 8 mg.	80	6/22/12	\$400.00	DS
Dilaudid 8 mg.	85	6/22/12	\$425.00	BS
Dilaudid 8 mg.	75	9/27/12	\$375.00	JF
Dilaudid 8 mg.	168	11/29/12	\$840.00	BM
Dilaudid 8 mg.	116	11/20/12	\$580.00	DC
Dilaudid 8 mg.	140	12/27/12	\$28.00	DC
Dilaudid 8 mg.	140	1/24/13	\$840.00	DC
Dilaudid 8 mg.	162	10/26/12	\$810.00	LF
Dilaudid 8 mg.	162	12/21/12	\$810.00	LF
Dilaudid 8 mg.	70	10/12/12	\$320.00	BK
Dilaudid 8 mg.	35	11/9/12	\$175.00	BK
Dilaudid 8 mg.	128	10/5/12	\$640.00	BK
Dilaudid 8 mg.	40	11/2/12	\$200.00	BK
Dilaudid 8 mg.	180	8/15/12	\$900.00	JB
Dilaudid 8 mg.	150	9/6/12	\$750.00	JB
Dilaudid 8 mg.	180	8/30/12	\$900.00	JF
Dilaudid 8 mg.	150	9/27/12	\$750.00	JF
Dilaudid 8 mg.	168	3/13/13	\$1,008.00	LB
Dilaudid 8 mg.	168	4/10/13	\$1,008.00	LB

Dilaudid 8 mg.	168	12/28/12	\$840.00	JS
Dilaudid 8 mg.	168	1/23/13	\$1,008.00	JS
Dilaudid 8 mg.	180	9/7/12	\$900.00	HH
Dilaudid 8 mg.	180	10/5/12	\$900.00	HH

The evidence shows that customers paid as much as \$1,008.00 for a month's worth of Dilaudid 8 mg.

Dr. Gordon's testimony explained that payment in cash for a controlled substance was always a red flag, even if a significant sector of the public did not have health insurance. Tr. 363. Paying in cash was a red flag, she testified, because it enabled evasion of processes established to alert a pharmacy that a prescription was being filled too soon. She stated, "A lot of drug-seekers only want to pay for their medications in cash because ... the computer systems, the insurance company will actually create your red flag for you to say if a prescription is refilled too soon, which means they've gone – obtained a prescription from another pharmacy." *Id.* at 297. She elaborated and provided a specific example: "[T]he insurance company will give you that red flag. Because they'll have a claim ... and they'll ... say, ... the patient just got this prescription yesterday from Walgreen's So ... the patrons will say, 'I don't want you to charge my insurance company.' That way it kind of eliminates that flag." *Id.* at 298-99.

In Dr. Gordon's opinion, the cash prices that Respondent charged its customers were as high as five times the cost Dr. Gordon would have expected. *Id.* at 362; *see also id.* at 417, 424, 502, 512. As Dr. Gordon concluded, "that to me means that maybe the pharmacist knew what was going on, and they were taking advantage of these patrons that were drug seeking." *Id.* at 362; *see also id.* at 464-65 (Concerning Respondent's initial charge of \$840 for a prescription and subsequent charge of \$1,008 for the same exact prescription on the next visit, Dr. Gordon suggested that "the pharmacist actually knew the prescriptions were diverted and ... was taking

advantage of that patron ... [b]ecause they knew they would pay whatever they needed to pay”). She explained that “the cost of that medication is high compared to what I’ve seen out in the field. That’s a very high cost. And between Fort Pierce, Miami, and Hallandale, you pass like a zillion pharmacies. ... It doesn’t make sense.” *Id.* at 362. According to Dr. Gordon, there was no notation made by the pharmacist on the prescriptions showing any attempt to resolve the red flags. *See, e.g., id.* at 364, 369, 371, 373, 374, 377, 389-90, 398, 404-05, 406, 411, 416, 421, 423, 424-25, 467; *see also id.* at 133 (DI testimony that he did not see notations on the prescriptions from Respondent “clearing” any red flags).

Mr. Fisher agreed that “[c]ustomers paying for their prescriptions with cash where other red flags of diversion are present” was a red flag. *Id.* at 756.

Respondent challenged Dr. Gordon’s cash price-level testimony based on her not having been in charge of purchasing controlled substances for resale for a small independent pharmacy. *Id.* at 502. Yet, I find Dr. Gordon’s testimony to be credible because she “actually looked up the national ... price.” *Id.* at 503. Respondent also challenged Dr. Gordon by stating that pharmacies where Dr. Gordon worked “like Walgreens, are getting discounts from the supplier on purchasing controlled medication.” *Id.* at 502. However, Dr. Gordon testified she was “99 percent sure” that discounts are not available for generic opioids. *Id.* at 503. Respondent presented no pricing data or other evidence refuting Dr. Gordon’s characterization of the higher-than-expected level of cash prices Respondent’s customers paid for controlled substance prescriptions. Further, Respondent did not present evidence to establish that its cash prices for controlled substances were consistent with the prices charged by other pharmacies similar to Respondent. Nor did it present evidence to establish that it set the level of its cash prices for controlled substances for a reason other than that its customers were willing to pay those prices.

Thus, I find no reason to reject Dr. Gordon's testimony. Rather, I shall credit it consistent with the CALJ's credibility determinations.

Based on all of the evidence in the record, I find that Respondent, without resolving the red flags, filled prescriptions that raised the red flag of customers paying cash for their prescriptions when other red flags were present. I further find that Respondent's customers were charged, and paid, exorbitantly high prices for their controlled substance prescriptions.

Customers Presenting New Prescriptions for Controlled Substances when They Should Not Have Finished Their Previous Prescription for that Drug ("Early Fills" or "Early Refills")

The last red flag the Government alleged in the Show Cause Order concerned early fills. According to the Government, Respondent filled prescriptions for controlled substances that the customers presented before the customers' previous prescription for that controlled substance should have been consumed. To support this allegation, the Government submitted 22 prescriptions. GX 14, at 1-33, 37-47.²⁷ Twelve of the prescriptions concerned one customer. The other ten prescriptions concerned five different customers. All 22 prescriptions were for Dilaudid 8 mg.

I reviewed the prescriptions the Government submitted and analyzed them according to the standard Dr. Gordon described in her testimony. GX 14; Tr. 436 ("[W]hat most pharmacies do ... [to determine whether a prescription is an early fill is] they start at when the first prescription was filled."); *see also* Tr. 429-67 (Dr. Gordon's testimony concerning GX 14), Tr. 75-76 (DI testifying that GX 14 consisted of true and accurate copies of documents he took from Respondent during the unannounced inspection), and Tr. 76-77 (DI testifying that GX 14 showed

²⁷ GX 14 included 24 prescriptions, but there were two copies of two of the prescriptions.

Respondent filled new schedule II controlled substance prescriptions before the customers' previous prescriptions should have been exhausted). I make these findings.

First, Respondent filled 12 prescriptions for BK, dispensing a total of 840 Dilaudid 8 mg. tablets, from July 26, 2012 through November 8, 2012. GX 14, at 1-33, 37-47.²⁸ Based on the dosing instructions, six tablets each day, 840 tablets should have lasted 140 days. The number of days from July 26, 2012 through November 8, 2012, the day before BK filled the last prescription in GX 14, was 105 days. Thus, in this period, Respondent dispensed to BK a 140-day supply of Dilaudid 8 mg. in 105 days. According to my analysis, Respondent filled all but one of them significantly early, from about at least 6 days early to up to about at least 29 days early. *Id.*

²⁸ Customer BK

<u>Drug</u>	<u>No. of tablets/SIG</u>	<u>Date Written</u>	<u>Date Filled</u>
Dilaudid 8 mg.	168 - 1 every 4 hrs. for pain	7/16/12	7/26/12
Dilaudid 8 mg.	168 - 1 every 4 hrs. for pain	8/13/12	8/13/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	9/7/12	9/10/12
Dilaudid 8 mg.	128 - 1 every 4 hrs. for pain	9/7/12	9/13/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	10/12/12	10/12/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	10/12/12	10/15/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	10/12/12	10/17/12
Dilaudid 8 mg.	8 - 1 every 4 hrs. for pain	10/12/12	10/17/12
Dilaudid 8 mg.	128 - 1 every 4 hrs. for pain	10/5/12	10/22/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	11/2/12	11/2/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	11/2/12	11/5/12
Dilaudid 8 mg.	40 - 1 every 4 hrs. for pain	11/2/12	11/9/12

I note that Respondent filled all four of the prescriptions that were written on the same day, October 12, 2012.

Further, one prescription for "chronic pain due to trauma," among other things, was written on July 16, 2012, yet BK did not have it filled until July 26, 2012. GX 14, at 1-2. Similarly, BK waited up to 16 days before filling another prescription for "chronic pain due to trauma," among other things. GX 14, at 17-18. BK's delay in filling such Dilaudid 8 mg. prescriptions casts doubt on the prescriptions' legitimacy.

Second, concerning the two Dilaudid 8 mg. prescriptions in GX 14 issued to JB, Respondent filled the second prescription at least one week early. *Id.* at 25-28.²⁹

Third, concerning the two Dilaudid 8 mg. prescriptions in GX 14 issued to LB, Respondent filled the second prescription at least 5 days early.³⁰

Fourth, Respondent filled the second Dilaudid 8 mg. prescription in GX 14 for JS at least 5 days early.³¹

Fifth, Respondent filled the second Dilaudid 8 mg. prescription in GX 14 for HH at least six days early.³²

According to Dr. Gordon, the prescriptions in GX 14 exhibited multiple red flags, yet Respondent filled them all. Tr. 429-67. For none of the prescriptions in GX 14 did Dr. Gordon testify that it included any notation recognizing or addressing red flags, that its red flags were resolvable, that it was a legitimate prescription, or that the pharmacist had exercised her corresponding responsibility to ensure that the prescription was issued for a legitimate medical

²⁹ Customer JB

<u>Drug</u>	<u>No. of tablets/SIG</u>	<u>Date Written</u>	<u>Date Filled</u>
Dilaudid 8 mg.	180 - 1 every 3 hrs. as needed	8/15/12	8/22/12
Dilaudid 8 mg.	150 - 1 every 3 hrs. as needed	9/6/12	9/6/12

³⁰ Customer LB

<u>Drug</u>	<u>No. of tablets/SIG</u>	<u>Date Written</u>	<u>Date Filled</u>
Dilaudid 8 mg.	168 - 1 every 4 hrs. as needed	3/13/13	3/18/13
Dilaudid 8 mg.	168 - 1 every 4 hrs. as needed	4/10/13	4/10/13

³¹ Customer JS

<u>Drug</u>	<u>No. of tablets/SIG</u>	<u>Date Written</u>	<u>Date Filled</u>
Dilaudid 8 mg.	168 - 1 every 4 hrs. as needed	12/28/12	12/31/12
Dilaudid 8 mg.	168 - 1 every 4 hrs. as needed	1/23/13	1/23/13

³² Customer HH

<u>Drug</u>	<u>No. of tablets/SIG</u>	<u>Date Written</u>	<u>Date Filled</u>
Dilaudid 8 mg.	180 - 1 every 4-6 hrs. as needed	9/7/12	9/14/12
Dilaudid 8 mg.	180 - 1 every 4-6 hrs. as needed	10/5/12	10/8/12

purpose by a practitioner acting in the usual course of professional practice. *Id.* at 437-38, 441, 442, 445-46, 446-47, 448-49, 450-51, 456, 458-59, 460-61, 464, 467.

Regarding these prescriptions and labels, Dr. Gordon testified that “the pharmacist was not exercising her corresponding responsibility, that most of these prescriptions should not have been filled or at least held until it was due to be filled.” *Id.* at 450. “However,” Dr. Gordon continued, “I wouldn’t have filled any of these to begin with.” *Id.* at 451. She explained: “The multiple red flags would alert any pharmacist that none of these prescriptions were legit because of the distance, that certain physician is a well-known pill mill writer, the Dilaudid 8, the odd quantities, ... the diagnosis of lumbago ... and paying cash. ... And the early fills.” *Id.* Specifically regarding the multiple prescriptions for BK that Respondent filled on October 17, 2012 and why, in Dr. Gordon’s experience, a patient would present two prescriptions for the same drug but different quantities on the same day, she testified: “I have no idea. That’s very unusual. I would not fill either one of these scripts. ... It’s a huge red flag for any pharmacist to get the same exact Dilaudid 8 from the same doctor on the same date. Huge red flag. No reasonable pharmacist would fill this.” *Id.* at 443.

Mr. Fisher agreed that an early fill was a red flag for diversion. *Id.* at 774. He identified early fill red flags in GX 14 on at least 13 occasions. *Id.* at 635-36, 637-38, 685, 692-93, 696 (two prescriptions filled on the same day), 698, 703, 704, 711, 714, 718, 721, 725, 727. Mr. Fisher testified that filling the two prescriptions on October 17, 2012 was “highly unusual.” *Id.* at 696. His testimony was that it was “reasonable” to fill a prescription two to three days early and that a pharmacy can do so. *Id.* at 700.

In Mr. Fisher’s view, early fill red flags were “resolvable,” meaning “there’s a number of explanations for an early fill.” *Id.* at 686; *see also id.* at 693, 704-05, 711, 715, 719, 722-23,

725-26. Being “honest,” as he prefaced his statement, he acknowledged that an attempt to secure more drugs was one of those explanations. *Id.* at 687. Regarding the prescriptions for BK, he testified: “A patient taking this medicine ... is not going to want to run out. ... [T]he pharmacy might ... only have 40 tablets ... on the twelfth, and they got some more in so they call the patient It also — ... to be honest, ... could be an attempt by a patient to secure more drugs.” *Id.* at 686-87. When asked if an early fill “can be reasonably explained where there is diversion or where there is no diversion,” Mr. Fisher responded that, “It could be either way.” *Id.* at 687. Mr. Fisher did not explain, however, why the physician would write all four of the prescriptions on the same day, let alone break them up into smaller quantities. Mr. Fisher also suggested that “the patient ... [may] only come down to that area once in a while for shopping, and they fill their prescriptions whenever they get down there.” *Id.* at 711. Mr. Fisher agreed that resolution of an early fill red flag “could be” and “should be” documented. *Id.* at 688.

Respondent’s Owner and PIC testified that an “early refill” is a red flag that “requires definite investigation.” *Id.* at 1165. She then stated, however, that the term “early refill” does not apply to a schedule II controlled substance and stated, regardless, that pharmacies are “obligated by the physician order.” *Id.* at 1167, 1170. She testified, “[T]here are two issues here, because why ... the patient is prevented early prescriptions? It’s not a refill on schedule IIs, so it’s not early refill, it’s an early fill. ... The doctor fills [sic] the order, you have to fill it. You’re obligated by the physician order.” *Id.*

In sum, both Dr. Gordon and Mr. Fisher identified about the same number of early fills in GX 14. They disagreed on how many days early a pharmacy could fill a controlled substance prescription without needing to resolve the suspicion. They also disagreed about the resolvability of early fills in general and in GX 14. Dr. Gordon testified that an early fill was not

legitimate and was not resolvable. Mr. Fisher testified that red flags due to early fills were resolvable, but admitted that an attempt to secure more drugs was one of the reasons for early fill requests. Mr. Fisher agreed that a pharmacist's resolution of an early fill should be documented.

Based on the testimony of Dr. Gordon and Mr. Fisher, I find that Respondent, without resolving the red flags, filled prescriptions early on at least 13 occasions. I find that the early fill-related testimony of Respondent's owner and PIC, that a prescription is a doctor's order and a pharmacist is "obligated" to fill a doctor's order, was Respondent's admission to an abdication of her corresponding responsibility.

Allegation that Respondent Was Unable to Readily Retrieve Prescriptions It Had Dispensed

The Show Cause Order alleged that Respondent committed six other violations, including that Respondent was unable to readily retrieve prescriptions it had dispensed. ALJX 1, at 7.

As already discussed, the DI testified that he conducted an unannounced inspection of Respondent on April 11, 2013. Tr. 36. At that time, he stated, he asked Respondent to retrieve 12 "problematic prescriptions" he had identified from a Florida Prescription Drug Monitoring Program query. *Id.* at 41-42. Those dozen prescriptions were for "anabolic steroid substances to patients that were not in the State of Florida." *Id.* at 42. The Show Cause Order alleged that the prescriptions were filled from February 15, 2012 to April 11, 2013, or less than two years before the date of the unannounced inspection. ALJX 1, at 7-8.

The DI testified that GX 21 consisted of Respondent's daily prescription log reports he obtained on the day of the unannounced inspection. Tr. 128. According to the DI, pages 1, 4, 6, 9, 13, and 16 of Respondent's daily prescription logs showed that Respondent had dispensed nine of the 12 prescriptions referenced in the Show Cause Order. *Id.* at 129-131; GX 21, at 1, 4,

6, 9, 13, and 16; ALJX 1, at 7-8. The DI further testified that the other three prescriptions appeared in the E-FORCSE report. Tr. 131; *see also* GX 20 (E-FORCSE query results).

The DI testified that Respondent “was never able to locate these prescriptions for me.” Tr. 42; *see also id.* at 49, 125. Instead, he testified that he learned of Respondent’s having located many of the missing prescriptions when he saw them in Respondent’s exhibits. *Id.* at 270-71; *see also* RX 12. Two of the requested prescriptions, he testified, were never located. Tr. 1185. According to Respondent’s Owner and PIC, “[t]hey was misfiled.” *Id.* at 1189. She testified that “if the number is assigned, it means that was prescription presented to the pharmacy. ... I know across the board, that it’s common that some prescriptions do get misfiled in pharmacies.” *Id.* at 1189-90.

The testimony of Respondent’s Owner and PIC confirmed Respondent’s failure to retrieve and provide the requested prescriptions to the DI on April 11, 2013. *See id.* at 846; *see also id.* at 1186 (The first time the prescriptions were provided to the Government was as an exhibit in this proceeding.). Respondent’s Owner and PIC offered excuses for that failure. *Id.* at 847-850.

I find that Respondent never provided the 12 requested prescriptions to the DI. I find that Respondent included ten of the 12 prescriptions in an exhibit for the hearing in this proceeding more than two years after they were requested during the unannounced inspection. I find that Respondent has still not provided the Government with two of the prescriptions that the DI requested on April 11, 2013.

Allegation that Respondent Shipped Controlled Substances Out-of-State Without Complying With Those States’ Non-Resident Pharmacy Requirements

Next, the Show Cause Order alleged that Respondent shipped controlled substances to four States (Alabama, Illinois, Kentucky, and Vermont) without complying with those States’

non-resident pharmacy requirements. ALJX 1, at 8. As support for the allegation, the Government submitted prescriptions for schedule III controlled substances (testosterone cypionate, testosterone cream, and stanozolol) that Respondent filled for seven customers whose addresses were in Alabama, Georgia, Illinois, Kentucky, Massachusetts, or Vermont. *See* GX 15; *see also* Tr. 87-88 (DI), Tr. 392-93 (Dr. Gordon), Tr. 731-32, 734 (Mr. Fisher). The Government also submitted seven FedEx shipping reports showing that Respondent shipped the prescriptions to customers outside the State of Florida. GX 15.

In further support of the allegation, the Government obtained certifications from Alabama, Illinois, Kentucky, and Vermont that Respondent had not complied with those States' out-of-state pharmacy requirements. *See* GX 24 (Alabama Board of Pharmacy Certification of Non-Licensure of Respondent for the period July 1, 1989 through April 29, 2015), GX 25 (Certification of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation that Respondent "does not now hold nor has ever held a license under the Pharmacy Practice Act of 1987" dated April 16, 2015), GX 26 (Kentucky Board of Pharmacy Executive Director letter dated April 14, 2015 stating that, "I have searched the Board records and do not find that ... [Respondent] has or ever has been issued a license/permit"), and GX 27 (Vermont Board of Pharmacy's Licensing Board Specialist Certification of Non-Licensure of Respondent for the period July 1, 1989 through April 13, 2015).

Respondent's Owner and PIC asserted that "out-of-state patients was out of question. That was for me," indicating that she would not have filled out-of-state prescriptions "[u]nder any circumstances, even the patient was really, really sick." Tr. 1023; *see also id.* at 44, 88-89 (DI's testimony that Respondent's Owner and PIC told him that Respondent never shipped a controlled substance out-of-state.). Yet, Respondent's Proposed Findings of Fact and

Conclusions of Law admitted that “[f]actually, ... Respondent was not registered in Alabama, Illinois, Kentucky and Vermont when it shipped control [sic] substances to these states.”

Respondent’s Proposed Findings of Fact and Conclusions of Law dated August 28, 2015 (hereinafter, Resp. Br.), at 4.

Based on the uncontroverted documentary evidence, which I find to be more persuasive than the testimony and statements of Respondent’s Owner and PIC to the contrary, and Respondent’s admission, I find that Respondent shipped controlled substances out-of-state to customers in Alabama, Illinois, Kentucky, and Vermont. Further, I find that, when Respondent shipped those controlled substances to out-of-state customers, it was not licensed or permitted to do so by the States of Alabama, Illinois, Kentucky, or Vermont.

Allegation that Respondent Filled Controlled Substance Prescriptions Not Containing All of the Information Required By 21 CFR 1306.05(a) and (f)

Next, the Show Cause Order alleged that Respondent filled controlled substance prescriptions that did not contain all of the information required by 21 CFR 1306.05(a). ALJX 1, at 9. As support for the allegation, the Government submitted nine prescriptions. GX 16. The DI testified that the patient’s full address was missing from six of the prescriptions. Tr. 99-101; *see also* GX 16, at 1, 3, 5, 7, 9, and 15. He testified that the prescriber’s DEA registration number was missing from four of the prescriptions. Tr. 99-101; *see also* GX 16, at 1, 11, 13, and 15. The DI testified that the directions for use were missing from one of the prescriptions. Tr. 99; *see also* GX 16, at 1. He testified that the prescriber’s address was missing from four of the prescriptions. Tr. 100-01; *see also* GX 16, at 7, 9, 11, and 13. The DI testified that the prescriber’s name was missing from two of the prescriptions, and that the prescriber’s signature was missing from one of them. Tr. 100-01; *see also* GX 16, at 11, 13, and 15, respectively.

My review and analysis of the 13 prescriptions in GX 8/8a identified information missing from prescriptions and discrepancies between information on some of the prescriptions and/or prescription labels and information on the customers' driver's licenses. *See, e.g.*, GX 8, at 15 and 17 (missing information in customer address); *id.* at 3-4 and 5-6 (discrepancies between the customer's address shown on the driver's license and shown on the prescription label); *id.* at 9-10 (discrepancies between the customer's address shown on the prescription and shown on the prescription label and driver's license); *see also* Tr. 614-15 (testimony of Mr. Fisher concerning missing information), Tr. 761-65 (testimony of Mr. Fisher concerning information discrepancies). In Mr. Fisher's opinion, Respondent did not exercise due care in entering customer addresses. Tr. 766.

Respondent's Owner and PIC admitted that Respondent filled the prescriptions in GX 16. *Id.* at 1196. She admitted that the patient's address was missing from five prescriptions. *Id.* at 1194-96; *see also* GX 16, at 3, 5, 7, 9, and 15. Respondent's Owner and PIC testified that the prescriber's DEA registration number was missing from three prescriptions, but that those numbers appeared on the prescription fill labels. Tr. 1195-96; *see also* GX 16, at 11, 13, and 15, and GX 16, at 14 and 16, respectively. Respondent did not dispute the facts underlying this allegation. *See, e.g.*, Resp. Exceptions, at 18 ("[I]t is true that twelve out of many hundreds of scripts lacked some of the information required.").

Having examined the prescriptions and all of the other evidence in the record concerning this allegation, I find the Respondent filled controlled substance prescriptions that did not contain all of the information required by 21 CFR 1306.05(a). I also find that Respondent's Owner and PIC admitted Respondent filled prescriptions not containing all of the information required by 21 CFR 1306.05(a).

Allegation that Respondent Filled Prescriptions Written for “Office Use” in Violation of 21 CFR 1306.04(b)

Next, the Show Cause Order alleged that Respondent filled prescriptions written for “office use” in violation of 21 CFR 1306.04(b). ALJX 1, at 10. To support this allegation, the Government submitted two Respondent “RX Order Forms,” one for testosterone and one for testosterone propionate, for which “Office Use” was written on the line designated for the patient name. *See* GX 17. The DI testified that these pages were controlled substance prescriptions written for “office use.” Tr. 252-53.

Respondent’s Owner and PIC testified that page 1 of GX 17 was a “prescription” for testosterone. *Id.* at 1200. She agreed that page 3 of GX 17 was a “copy of a prescription” for testosterone. *Id.* at 1202; *see also* Resp. Br., at 10 (“Factually, Respondent did fill the prescriptions alleged in OSC ¶ 6 for ‘office use.’”). Respondent’s Owner and PIC further testified that the entity that completed and submitted the “RX Order Forms” was engaged in hormone replacement therapy and wanted to “see how the patient responds” and “make sure that the patient don’t have allergic reaction on the prescription before they dispense it.” Tr. 1199; *see also id.* at 1201. Her testimony acknowledged that Respondent “delivered” the testosterone “prescribed” on page 1 of GX 17. *Id.* at 1200. Regarding the prescription depicted on page 3 of GX 17, however, Respondent’s Owner and PIC testified to having “a flashback,” stating that, “I really remember that I don’t give them that cypionate.” *Id.* at 1203.

I find that Respondent admitted filling at least two controlled substance “prescriptions” for “office use” and delivering at least one of them to an entity engaged in hormone replacement therapy for the purpose of allergy testing.

Allegation that Respondent Filled Prescriptions Written by Physicians for the Physicians’ Personal Use in Violation of Florida Statute § 458.331(r)

Next, the Show Cause Order alleged that Respondent filled prescriptions written by physicians for the physicians' personal use in violation of Florida Statute § 458.331(r). ALJX 1, at 10. As support for this allegation, the Government submitted 12 documents that, according to the DI, included "controlled substance prescriptions" which doctors wrote "to themselves." Tr. 106; *see also* GX 18. One prescription was written on Respondent's "RX Order Form" and had nothing written in the "patient" information boxes. GX 18, at 3. The labels associated with this "prescription" showed the same name for the patient and the prescriber. *Id.* at 4. Respondent admitted that, "Factually, Respondent did fill the prescriptions alleged in OSC, ¶ 7 written by physicians for the physicians' personal use." Resp. Br., at 16.

I find that Respondent admitted filling six "prescriptions" which doctors wrote "to themselves," and that the "prescriptions" were for controlled substances.

Allegation that Respondent Violated Florida State Law by Failing to Report Some Prescriptions to E-FORCSE in Violation of Florida Statute § 893.055(4)

Finally, the Show Cause Order alleged that Respondent failed to comply with Florida law by failing to report some prescriptions to E-FORCSE. ALJX 1, at 10-11; *see* Fla. Stat. § 893.055(4) (2012). In support of this allegation, the Government submitted six Dilaudid 8 mg. prescriptions written by the same doctor from July through November of 2012. *See* GX 19. The DI obtained these prescriptions during his unannounced inspection of Respondent. Tr. 107; ALJX 1, at 11. The DI testified that none of these six prescriptions was reported to E-FORCSE according to his analysis of the results of his E-FORCSE query for the period February 14, 2012 to February 4, 2013. Tr. 108-10, 115; *see also* GX 20 (E-FORCSE query results).

Further, in addition to doing his own query, the DI explained that he asked the E-FORCSE program manager to "do a back-end query to see if these prescriptions were ever uploaded or any errors or ... any attempts were made for these prescriptions." Tr. 109; *see also*

id. at 119. As further support for this allegation, the Government introduced the certified response the DI received from the program manager stating that, “I certify, none of the prescriptions ... were uploaded.” GX 23, at 1 (Letter from E-FORCSE Program Manager to DI dated April 2, 2015); *see also* Tr. 118. The Program Manager’s letter, the DI explained, “shows ... that ... [the six prescriptions] were never uploaded” to E-FORCSE and that there were no uploading attempts that failed due to an error. Tr. 118. The DI also testified that the second page of GX 23 “shows the uploads that ... [Respondent] did in that timeframe, and where those [six] prescriptions should have fallen into if ... [Respondent] had, in fact, uploaded them.” *Id.* The DI concluded from this evidence that “these [six] prescriptions were never entered” into E-FORCSE. *Id.* at 123.

Respondent’s Owner and PIC did not challenge the Government’s contention that the six prescriptions in GX 19 did not appear in E-FORCSE. Her testimony included that “I fully believe it was actually entered”; “I do not know. I did the fair attempt to provide all Schedule prescriptions, and if other prescription was in E-FORCSE, this prescription should be in E-FORCSE”; “I know that I made a fair attempt to submit this prescription along with other prescription that was accumulated for that week. That was in a compiled file”; and “I can fairly testify that I did the best effort to submit the prescription to the E-FORCSE.” *Id.* at 898, 914-15, 922-23, 935, respectively.

I find that Respondent did not present evidence contesting the Government’s allegation that six of the controlled substance prescriptions it filled did not appear in E-FORCSE. I find that Respondent filled, but did not report to E-FORCSE, six controlled substance prescriptions for Dilaudid 8 mg. written by the same doctor from July through November of 2012.

DISCUSSION

Under Section 304 of the Controlled Substances Act (hereinafter, CSA or Act), “[a] registration ... to ... distribute[] or dispense a controlled substance ... may be suspended or revoked by the Attorney General upon a finding that the registrant ... has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.” 21 U.S.C. § 824(a)(4). In the case of a retail pharmacy, which is a “practitioner” under 21 U.S.C. § 802 (21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing ... controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the ... distribution[] or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). [T]hese factors are ... considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003).

It is well settled that I “may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether” to revoke a registration. *Id.*; see also *MacKay v. Drug Enforcement Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enforcement Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enforcement Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); see also *Hoxie*, 419 F.3d at 482. “In short, ... the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on

protecting the public interest; what matters is the seriousness of the registrant's misconduct."

Jayam Krishna-Iyer, M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

Under DEA's regulation, "[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to ... 21 U.S.C. [§] 824(a) ... are satisfied." 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case was confined to Factors Two and Four.³³ I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public

³³ As to Factor One, there is no evidence that the Florida Department of Health or the Florida Board of Pharmacy made a recommendation concerning Respondent and the matter before me. Respondent provided several filings, from administrative proceedings and from Respondent's lawsuit against the Florida Department of Health, involving its permit to function as a community pharmacy and the compounding side of its business at its registered location and elsewhere in Florida. According to Respondent's cover letter, it provided this material due to an Order during the Prehearing Conference on April 14, 2015. ALJX 12, at 1. Material in Respondent's submission indicated that the Florida Board of Pharmacy (1) found Respondent had waived the right to request a hearing by failing to respond in a timely manner to the Administrative Complaint against it, (2) approved, adopted, and incorporated the Administrative Complaint's factual allegations, and (3) disciplined Respondent, placing it on probation for two years and requiring quarterly inspections. *Id.* at 20-21. The materials do not establish that Respondent lacks State authority or contain a recommendation one way or another.

While there is no evidence that Florida has revoked Respondent's license, DEA has held repeatedly that a registrant's possession of a valid State license is not dispositive of the public interest inquiry. *Lon F. Alexander, M.D.*, 82 FR 49,704, 49,724 n.42 (2017) (citing *Mortimer Levin, D.O.*, 57 FR 8680, 8681 (1992)). As DEA has long held, "[t]he Controlled Substances Act requires that the Administrator ... make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest." *Alexander*, 82 FR at 49,724 n.42 (citing *Levin*, 57 FR at 8681).

As to Factor Three, there is no evidence that Respondent has a "conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. § 823(f)(3). However, as the Agency has noted, there are any number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010), *pet. for rev. denied, MacKay v. Drug Enforcement Admin.*, 664 F.3d 808 (10th Cir. 2011). The DEA has therefore held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.*

interest.” 21 U.S.C. § 823(f). I further find that Respondent failed to produce sufficient evidence to rebut the Government’s *prima facie* case.

Specifically, I find that the record contains substantial evidence that Respondent’s pharmacists violated their corresponding responsibility when they dispensed multiple prescriptions. I also find there is substantial evidence in the record that Respondent was unable to readily retrieve prescriptions it had dispensed, shipped controlled substances out-of-state without complying with States’ non-resident pharmacy requirements, and filled controlled substance prescriptions that did not contain all the information required by 21 CFR 1306.05. Accordingly, I agree with the CALJ that Respondent’s registration should be revoked. Further, I agree with the CALJ’s conclusions concerning Respondent’s non-acceptance of responsibility and the appropriate disposition of Respondent’s efforts to show its remedial measures. R.D., at 58. For the reasons set out below, I will order that Respondent’s registration be revoked and that any pending application of Respondent be denied.

Factors Two and/or Four – The Registrant’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Allegations that Respondent Failed to Exercise Its Corresponding Responsibility When It Dispensed Controlled Substances Pursuant to Prescriptions Not Issued in the Usual Course of Professional Practice or for a Legitimate Medical Purpose

Under the CSA, it is “unlawful for any person knowingly or intentionally ... to ... distribute[] or dispense, or possess with intent to ... distribute[] or dispense, a controlled substance” “[e]xcept as authorized” by the Act. 21 U.S.C. § 841(a)(1). A pharmacy’s registration authorizes it to “dispense,” or “deliver a controlled substance to an ultimate user ... by, or pursuant to the lawful order of ... a practitioner.” 21 U.S.C. § 802(10).

According to the CSA’s implementing regulations, a lawful controlled substance order or prescription is one that is “issued for a legitimate medical purpose by an individual practitioner

acting in the usual course of his professional practice.” 21 CFR 1306.04(a). While the “responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, ... a corresponding responsibility rests with the pharmacist who fills the prescription.” *Id.* The regulations establish the parameters of the pharmacy’s corresponding responsibility.

An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. [§] 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. As the Supreme Court has explained in the context of the Act’s requirement that schedule II controlled substances may be dispensed only by written prescription, “the prescription requirement ... ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse ... [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

The Government must show that the pharmacist acted with the requisite degree of scienter to prove a violation of the corresponding responsibility regulation.³⁴ *See Hills Pharmacy, LLC*, 81 FR 49,816, 49,835 (2016). According to Agency precedent, the Government may prove a violation by showing either that: (1) the pharmacist filled a prescription notwithstanding her actual knowledge that the prescription lacked a legitimate medical purpose;

³⁴ The Show Cause Order alleged that “Respondent” violated its corresponding responsibility. Respondent and the Government stipulated that: “The Respondent is owned and operated by Veronica Taran.” Further, Respondent’s Owner and PIC admitted that she is Respondent’s pharmacist-in-charge and Respondent’s only pharmacist. Tr. 1012 (“[I]n this particular practice, because there’s only me, there’s nobody else there, like, there’s no other pharmacist there.”). When asked by her counsel whose responsibility it was to resolve any red flags, she testified that “[u]ltimate responsibility lies up me as the pharmacist and pharmacist-in-charge.” *Id.* at 1045. Thus, for purposes of finding and attributing liability in this case, I find that the actions and inactions of Respondent’s Owner and PIC were the actions and inactions of Respondent.

or (2) the pharmacist was willfully blind or deliberately ignorant to the fact that the prescription lacked a legitimate medical purpose. *Id.* To establish that a pharmacist acted with willful blindness, the Government must prove that the pharmacist had a subjective belief that there was a high probability that a fact existed and she took deliberate actions to avoid learning of that fact. *Id.* (quoting *Global-Tech Applications, Inc., v. SEB S.A.*, 563 U.S. 754, 769 (2011)); *see also United States v. Henry*, 727 F.2d 1373, 1378 (5th Cir. 1984) (citing *United States v. Hayes*, 595 F.2d 258 (5th Cir.), *cert. denied*, 444 U.S. 866 (1979) (rejecting challenge that the regulation was unconstitutionally vague)) (“What is required by him [the pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice. ... [A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.”).

The Government did not allege that Respondent dispensed the prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation as “evidenced” by its “dispensing of controlled substances despite the presence of red flags of diversion that ... [it] failed to clear prior to dispensing the drugs.” ALJX 1, at 1-2 (citing *Holiday CVS*); *see also* Government’s Proposed Findings of Fact and Conclusions of Law dated August 28, 2015 (hereinafter, Govt. Br.), at 15-16.

As discussed above, the testimony of Dr. Gordon, as well as testimony offered by Respondent’s own witness, Mr. Fisher, supported the Government’s allegations that the seven different factual circumstances the Government alleged to be “red flags of diversion” existed as

alleged, and that Respondent did not resolve them before dispensing controlled substances.³⁵ See also R.D., at 9 (“Dr. Gordon testified that she will not dispense a controlled medication in the face of an unresolved red flag”) and at 13 (“Mr. Fisher acknowledged that none of the Respondent’s pharmacy paperwork reflected any documentation that red flags were resolved prior to dispensing and that he did not know whether they were ever resolved.”). Further, as discussed above, the CALJ recommended crediting that documentary and testimonial evidence. I find credible the testimony of Dr. Gordon and, to the extent he agreed with Dr. Gordon, Mr. Fisher that Respondent filled controlled substance prescriptions that raised “red flags” without resolving, and documenting the resolution of, those red flags.

Prior Agency decisions found that prescriptions with the same “red flags” at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency’s corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions’ illegitimacy.³⁶ 21 CFR 1306.04(a). See, e.g., *Hills Pharmacy*, 81 FR at 49,836-39 (multiple customers filling prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; two short-acting opiates prescribed together; long distances; drug cocktails; payment by cash); *The Medicine Shoppe*, 79 FR 59,504, 59,507, 59,512-13 (2014) (unusually large quantity of a controlled substance; pattern prescribing;

³⁵ For example, Respondent’s Owner and PIC even testified that it was not a red flag “by itself” for a customer to travel over 100 miles from their Florida home to Respondent to fill a controlled substance prescription. Tr. 1028. Indeed, regarding red flags, her testimony was that red flags were a stumbling block. Respondent’s Owner and PIC said that “just by strictly following these red flags, it will prevent legitimate patient from obtaining the medication.” *Id.* at 1108.

³⁶ Agency precedent has defined the term “red flag” to mean “a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription.” *Hills Pharmacy*, 81 FR at 49,839. This precedent, in conjunction with the terms of the corresponding responsibility regulation, means that the suspicious circumstances presented by the red flags must rise to the level necessary to support a finding that the pharmacist acted with willful blindness.

irregular dosing instructions; drug cocktails); *Holiday CVS*, 77 FR 62,316, 62,317-22 (2012) (long distances; multiple customers filling prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy*, 75 FR 66,149, 66,163-65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions).

Agency precedent has made clear that, when presented with a prescription clearly not issued for a legitimate medical purpose, a pharmacist may not intentionally close her eyes and thereby avoid positive knowledge of the real purpose of the prescription. *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 FR 28,667, 28,670 (2015). Yet, that is exactly what Respondent's Owner and PIC did.

As I detailed above, the testimony of Respondent's Owner and PIC acknowledged that schedule II controlled substances are highly risky and are subject to "a lot of diversion." Tr. 1129, 1116 (respectively). She also specifically testified that a prescription for a large quantity of a schedule II controlled substance raised red flags. *Id.* at 881, 882, 887. Yet, she admitted failing to address such schedule II prescriptions presented to her pharmacy in a fashion consistent with her testimony. *Id.* at 1132-39. She did not explain or justify her conscious and deliberate choice to avoid learning legitimacy-related information about schedule II prescriptions that she knew were "highly risky," prone to diversion, and raised red flags. These acknowledgements and failures clearly show her subjective belief of a high probability that the various schedule II prescriptions presented to her were not legitimate and her deliberate actions to avoid learning of their illegitimacy.

Further, although Respondent challenged Dr. Gordon's expertise to testify that it charged exorbitantly high prices for controlled substances, Respondent did not offer any price-related evidence disputing Dr. Gordon's testimony. The evidence in the record that Respondent charged exorbitantly high prices for controlled substance prescriptions is further proof that Respondent knew or subjectively believed that there was a high probability that its customers were either abusing or diverting those controlled substances. *See also id.* at 362 (Dr. Gordon's testimony that "maybe the pharmacist knew what was going on, and they were taking advantage of these patrons that were drug seeking.") and *id.* at 465 (Dr. Gordon's testimony suggesting that Respondent "knew ... prescriptions were [being] diverted" and "was taking advantage of that patron ... [b]ecause they knew they would pay whatever they needed to pay" to fill the prescription.)

The so-called "proper steps" for handling schedule II prescriptions that Respondent's Owner and PIC constructed were actually abdications of her corresponding responsibility. According to Respondent's Owner and PIC, her responsibility, when presented with a controlled substance prescription, was limited to (1) making sure the prescriber's medical license was current; (2) checking the prescriber's DEA registration against the controlled substance in the prescription; (3) obtaining the patient's signature on the Relationship Affidavit as alleged verification of a *bona fide* doctor-patient relationship; and (4) validating that the prescriber actually signed the prescription, as opposed to its having been rubber stamped. These steps, however, do not constitute an independent exercise of professional judgment by a pharmacist evaluating the legitimacy of highly suspicious controlled substance prescriptions such as those at issue here. They were clearly insufficient to determine the legitimacy of schedule II prescriptions that Respondent's Owner and PIC herself characterized as "highly risky" and prone

to diversion. Instead, they constituted a pharmacist's abdication of responsibility for a legitimacy assessment.

As for checking the currency of the prescriber's medical license and DEA registration, this is not enough as a prescriber must generally hold both a license and registration to even issue a prescription under the CSA. 21 CFR 1306.03(a). The fact that a practitioner possesses the requisite authority does not, however, mean that he/she acted in the usual course of professional practice in issuing any particular prescription and that the prescription was issued for a legitimate medical purpose. *Cf. Krishna-Iyer*, 74 FR at 463.

As for the "proper step" of having a customer sign the Relationship Affidavit, Respondent's Owner and PIC did not explain why it was reasonable for her to expect customers who were drug seekers to understand the content of that document. Moreover, even if the customers did understand the document, she offered no explanation as to why her customers would be honest and truthful in answering the questions if they were seeking controlled substances to either personally abuse or divert to others.³⁷

Lastly, the "proper step" of ensuring that the prescription was not "signed" by a rubber stamp might have showed that the prescription was not an outright fraud, but it did nothing to ensure that the prescription was issued for a legitimate medical purpose. 21 CFR 1306.04(a).

Respondent's Owner and PIC also testified regarding the five CII/CIII Rx Verification Forms which were part of Respondent's "patient files" (*see* RXs 6 and 10) and "kept in the regular course of business."³⁸ Tr. 824-25. She also stated that they "assisted ... [her] to resolve

³⁷ Further, I find that the high prices Respondent charged for controlled substances, as discussed above, suggest that Respondent knew its customers were either abusing or diverting them.

³⁸ Respondent submitted one other CII/CIII Rx Verification Form. RX 5, at 9.

the red flags.” *Id.* at 824. Yet, neither she nor Respondent explained why Respondent submitted only five such forms from its “patient files” when the Government’s evidence included 60 prescriptions and 29 patients. Moreover, while the forms indicated that the prescriptions were actually written by a physician, that the physician saw and physically examined the patient, and that there were diagnosis codes, the forms contained no additional documentation as to what circumstance prompted Respondent to contact the physician and what information the physician’s office provided which led the pharmacist to approve and fill the prescription. Thus, at most, the forms establish with respect to these five patients that Respondent verified each prescription with its issuer. However, long-standing case law has explained that “[v]erification by the issuing practitioner on request of the pharmacist . . . is not an insurance policy against a fact finder’s concluding that the pharmacist had the requisite knowledge despite a purported but false verification.” *United States v. Henry*, 727 F.2d at 1378 (quoting *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979)). In sum, Respondent’s CII/CIII Rx Verification Forms are insufficient and do not alter my finding that Respondent violated the corresponding responsibility regulation.

The Government also submitted prescriptions, in support of the Show Cause Order’s corresponding responsibility allegation, that did not involve schedule II controlled substances. As discussed above, the controlled substance was testosterone cypionate and the same doctor wrote all of the prescriptions on the same day. GX 10. Respondent filled all of those prescriptions within the period of about an hour and a half. *Id.* Dr. Gordon, Mr. Fisher, and Respondent’s Owner and PIC agreed that these prescriptions raised red flags. Although Respondent’s Owner and PIC stated that she resolved the red flags, she did not produce any documentary evidence to support her statement and, thus, I did not afford her statement any

weight. As discussed above, I found that Respondent also filled these prescriptions in the face of their red flags. The fact that Respondent's Owner and PIC acknowledged these prescriptions' red flags clearly evidenced her subjective belief of a high probability that these schedule III prescriptions were not legitimate. The fact that she simply filled them showed that she took deliberate actions to avoid learning of their illegitimacy.

Accordingly, I find the Government has proved by substantial evidence that controlled substance prescriptions Respondent, by Respondent's Owner and PIC, filled were not prescriptions issued in the usual course of professional treatment, yet Respondent, by Respondent's Owner and PIC, knowingly filled, or filled with willful blindness, those prescriptions in violation of the corresponding responsibility regulation. 21 CFR 1306.04(a); *see also Hills Pharmacy*, 81 FR at 49,835; *Superior Pharmacy I and Superior Pharmacy II*, 81 FR 31,310, 31,335 (2016); *The Medicine Shoppe*, 79 FR at 59,515-16; *East Main Street Pharmacy*, 75 FR at 66,163-65.³⁹

I considered Respondent's claim that Dr. Gordon's testimony should not be credited because "she never worked as a pharmacist in an independent pharmacy" such as Respondent and, therefore, "her dispensing, managing and purchasing experience is not comparable to those of [Respondent's Owner and PIC]." Resp. Br., at 37-38. I reject this claim. I have already set out my credibility determinations, which are based on the credibility recommendations of the

³⁹ This case is different from *Superior Pharmacy I and Superior Pharmacy II* where the Government's evidence was insufficient to establish a corresponding responsibility violation even though Respondent dispensed controlled substance prescriptions in the face of unresolved red flags such as long distances, multiple people presenting identical or very similar prescriptions from the same prescriber on the same day, drug cocktails, two people in the same household or with the same address needing the exact same drugs, and payment by cash. 81 FR at 31,336. The Government's evidence in that case consisted only of the prescriptions allegedly dispensed without documentation of the resolution of red flags. As explained in that decision, there was no applicable law or rule requiring that documentation of the resolution of a red flag be placed on the prescription. Here, by contrast, the documentary and testimonial evidence made abundantly clear that Respondent did not carry out its corresponding responsibility.

CALJ. Those determinations afford Dr. Gordon's testimony the appropriate weight in these proceedings regarding the practice of pharmacy in Florida. Further, Respondent's claim is simply incorrect. The corresponding responsibility of a pharmacist is the same whether the pharmacist practices at an independent pharmacy or in a chain pharmacy. In other words, the size or corporate status of the pharmacy in which a pharmacist practices does not dictate the scope of a pharmacist's obligation under federal law.

I reject Respondent's claim that the Government arbitrarily designated customers as having travelled long distances "since it is not relying on any statutory enactment, federal or state to make such a designation." *Id.* at 33. Even Respondent's witness, Mr. Fisher, agreed that customers traveling long distances to fill prescriptions is a red flag. Tr. 754; *see also* R.D., at 47.

I considered Respondent's claim that Dr. Gordon's testimony about pattern prescribing created "an unrecognized standard under, both, case law and the Florida statutory law." Resp. Br., at 38. I find that Respondent's claim is without merit. Numerous agency and court cases have recognized that pattern prescribing is a red flag. *See, e.g., The Medicine Shoppe*, 79 FR at 59,512; *see also United States v. Durante*, No. 11-277, 2011 WL 6372775, at *3 (D.N.J. Dec. 20, 2011) ("This is sufficient to establish probable cause to believe that Defendant was engaged in an extensive pattern of prescribing controlled substances without a legitimate medical purpose to a broad group of patients in his medical practice.'). Further, as already discussed, even Respondent and Respondent's own witness, Mr. Fisher, eventually admitted that pattern prescribing was a red flag of diversion.

During the hearing, Dr. Gordon testified about the level of the cash price Respondent charged for some prescriptions, including in comparison to what another pharmacy might charge. *See, e.g.,* Tr. 400, 406, 410-11, 413, 415, 417-18. Respondent's Counsel objected, stating that

“the expert is testifying in price difference against what a normal pharmacist, quote, unquote, would charge versus what ... [Respondent] charged for certain drugs, drug being Dilaudid.” *Id.* at 419. He continued his objection by stating that, “I just reviewed the prehearing statement provided by the Government, and there is no mention that their expert is going to get into the price ... differentiation ... between a normal pharmacy and ... [Respondent].” *Id.* at 419-20. Respondent’s Counsel subsequently elicited from Dr. Gordon that she was “never in charge of purchasing controlled substances for resale for a small independent pharmacy.” *Id.* at 482; *see also* Resp. Exceptions, at 2. The CALJ’s recommendation was that “the Government did not adequately notice the relative price charged for the medication ... [because] [t]he Agency recently imposed an increasingly rigorous standard of notice.” R.D., at 10 n.60.

I reject the Exception. As to the issue of notice, for reasons previously explained, the Agency has rejected the notion that the “Agency recently imposed an increasingly rigorous standard of notice on its administrative prosecutors.” *See, e.g., Wesley Pope, M.D.*, 82 FR 14,944, 14,946 n.4 (2017). Here, the Government in its Prehearing Statement gave notice that Dr. Gordon would testify about “patients willing to pay exorbitant prices” as well as the relative price charged for the medication by Respondent. ALJX 5 (Govt. Prehearing Statement), at 11. Accordingly, I find that the Government provided adequate notice that the prices charged by Respondent would be at issue in the proceeding.

To the extent Respondent argues that I should give no weight to Dr. Gordon’s testimony, I reject its argument that I should reject her testimony because she has never purchased controlled substances for a small pharmacy. Indeed, Dr. Gordon specifically testified that she “actually looked up the national ... price.” *Id.* at 503.

In its Exceptions, Respondent argues that the “absence of Respondent’s corresponding exhibit should not be interpreted as an absence of records,” and that “it simply means that ... the records in Respondent’s possession are the same records as contained in a corresponding Government’s exhibit.” Resp. Exceptions, at 8 n.10. In this Exception, Respondent indicates its dispute with the Government’s allegation that “Respondent failed to exercise its corresponding responsibility under the regulations by failing to acknowledge and resolve red flags related to a pattern of a doctor prescribing the exact same medication in a cookie-cutter fashion to multiple patients on the same day.” Resp. Exceptions, at 8. As the CALJ noted, however, Respondent’s Owner and PIC “conceded that the paperwork furnished to the DIs at the April 11th Inspection did not memorialize any attempts to resolve this red flag and agreed that she did not have any paperwork documenting her identification or resolution of the issue.” R.D., at 49 (citing Tr. 1094). While Respondent’s Exception purports to correlate its “corresponding exhibit” with the Government’s evidence, Respondent fails to explain the many instances in which Respondent simply did not offer documentary evidence to support the bald assertions of Respondent’s Owner and PIC that Respondent complied with the corresponding responsibility regulation. *See, e.g.*, R.D., at 49-50 (“[I]t is difficult to reconcile the multiple areas where the Respondent’s recordkeeping system ... had the capacity to note details such as red flag resolution with the absence of any documented indication that this, or any other red flags, were analyzed and resolved.”).

Further, this Agency has applied, and I apply here, the “adverse inference rule.” As the D.C. Circuit explained, “Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.” *Int’l Union, United Auto., Aerospace & Agric. Implement*

Workers of Am. (UAW) v. Nat'l Labor Relations Bd., 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance v. District of Columbia*, 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondent's decision not to provide records gives rise to an inference that any such evidence is unfavorable to Respondent. In any event, as explained above, the records Respondent did provide concerning the Government's allegations were insufficient to rebut those allegations.

Respondent suggested throughout the hearing and in its briefs that the Government's case was deficient. *See, e.g.*, Resp. Exceptions, at 9-10, 11, 13, 14, 15, and 16-17. Having reviewed and considered all of Respondent's claims and arguments, I find that none of them has merit. Adoption of any of them would undermine this Agency's regulatory mission, and I decline to rule against long-standing precedent.

For example, in its Exceptions, Respondent argues that the Government's Expert "admitted that she has no evidence that . . . any of the prescriptions . . . were diverted or somehow used for or with illicit purposes." Resp. Exceptions, at 11. Notwithstanding the Government's Expert's testimony, there is ample circumstantial evidence that the prescriptions at issue in this proceeding were issued by a physician acting outside of the usual course of professional practice. The circumstantial evidence includes that the prescriptions were for large quantities of Dilaudid 8 mg., a highly abused narcotic; that customers were traveling long distances; and that many of the customers were paying cash and exorbitantly high prices. In other instances, the evidence showed that customers were obtaining early fills of prescriptions.

Second, Respondent suggests that the Government's failure to prove the prescribing doctors were not licensed or registered at the relevant time, or otherwise "unable to lawfully issue the prescription[s]," somehow exonerated Respondent. *See, e.g.*, Resp. Exceptions, at 13.

Respondent cites no legal authority for this Exception. Indeed, it is fatally flawed because it suggests that Respondent's corresponding responsibility is alleviated by the prescriber's medical license, controlled substances registration, or other credential. As the language of the regulation makes clear, while the prescribing practitioner is responsible for the proper prescribing and dispensing of a controlled substance, a corresponding responsibility rests with the pharmacist who fills a controlled substance prescription, and the pharmacist who knowingly fills a "purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR 1306.04(a). Thus, contrary to Respondent's suggestion, the good order of the prescribing practitioner's license, registration, or other credential does not alleviate the pharmacist's corresponding responsibility or exonerate the pharmacist in any way. I reject Respondent's Exception.

Third, Respondent claims that the Government failed to prove the existence of any indicator of controlled substance abuse specified in Fla. Admin. Code r. 64K-1.007 (adopted May 21, 2012).⁴⁰ *See, e.g.*, Resp. Exceptions, at 14-17. Respondent cites no legal basis for its claim that the provisions of this State Administrative Code section, that were not even in effect during the entire period covered by the Show Cause Order, are determinative of liability under Federal law. I reject Respondent's Exception.

Finally, Respondent suggested that the Government's case must fail because the DI did not meet with any prescriber or speak with any customer. *See, e.g.*, Resp. Br., at 35, 37.

⁴⁰ According to this provision, the E-FORCSE Program Manager "may provide relevant information to the identified health care practitioners who have prescribed or dispensed controlled substances" to an individual "who within a 90-day time period ... obtains a prescription for a controlled substance ... from more than one prescriber ... and ... is dispensed a controlled substance ... from five or more pharmacies."

Respondent did not elaborate on its argument or cite any legal precedent for it. Again, Agency precedent has made clear that Respondent's argument is mistaken.⁴¹ Accordingly, I reject it.

Allegation that Respondent Filled Controlled Substance Prescriptions Not Containing All of the Information Required by 21 CFR 1306.05(a) and (f)

The Show Cause Order alleged that Respondent filled controlled substance prescriptions that did not contain all the information required by 21 CFR 1306.05(a) and (f). According to that regulation, a "corresponding liability rests upon the pharmacist ... who fills a prescription not prepared in the form prescribed by DEA regulations." 21 CFR 1306.05(f). Among other things, those DEA regulations require that controlled substance prescriptions be "dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." 21 CFR 1306.05(a). As found above, Respondent filled controlled substance prescriptions that did not contain all of the information required by 21 CFR 1306.05.

As discussed above, the uncontroverted evidence is not only that Respondent violated this regulation, but that Respondent admitted violating this regulation. I find, based on all of the evidence in the record, that Respondent violated 21 CFR 1306.05(a) by filling multiple controlled substance prescriptions that were not prepared in the form prescribed by DEA regulation.

Allegation that Respondent Filled Prescriptions Written for "Office Use" in Violation of 21 CFR 1306.04(b)

⁴¹ "While it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose, Respondent ignores that the invalidity of a prescription can be proved by circumstantial evidence." *Hills Pharmacy*, 81 FR at 49,836, n.33.

The Show Cause Order alleged that Respondent violated 21 CFR 1306.04(b) when it filled prescriptions issued for “an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.” ALJX 1, at 10. As explained above, GX 17 included two “RX Order Forms” that Respondent referred to as “prescriptions” and, pursuant to at least one of them, admitted delivering controlled substances to an entity engaged in hormone replacement therapy for the purpose of allergy testing. Based on Respondent’s admissions, I find that Respondent filled prescriptions issued in violation of 21 CFR 1306.04(b).⁴² I note, however, that 21 CFR 1306.04(b), the provision the Government cited in the Show Cause Order, prohibits the issuance, not the filling, of prescriptions.

Neither the Show Cause Order nor the Government Prehearing Statement cited a statutory or regulatory provision that prohibited the filling of a prescription issued in violation of 21 CFR 1306.04(b). In addition, the Government did not discuss the “office use” allegation, let alone address the legal sufficiency of this allegation in the Show Cause Order or in the Government Prehearing Statement. I find that the Government did not allege a legal basis for the revocation or suspension of Registrant’s registration upon a finding that Registrant “filled” prescriptions issued in violation of 21 CFR 1306.04(b).

Thus, while I find that Respondent admitted filling prescriptions issued in violation of 21 CFR 1306.04(b), I also find that the Government did not comply with the requirement that the Show Cause Order “contain a statement of the legal basis for ... the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.” 21 CFR

⁴² After admitting that it filled “the prescriptions alleged” in the Show Cause Order, Respondent argued that its actions were “legal and proper” under 21 CFR 1307.11(a), the so-called 5% Rule. Resp. Br., at 15-16. Since I find that the Government did not allege a legal basis for the “office use” allegation, I need not address Respondent’s argument concerning 21 CFR 1307.11(a).

1301.37(c). Thus, I will not give any weight in the public interest assessment to Respondent's admission that it filled prescriptions issued in violation of 21 CFR 1306.04(b).

Allegation that Respondent Filled Prescriptions Written by Physicians for the Physicians' Personal Use in Violation of Florida Statute § 458.331(r)

According to the Show Cause Order, Respondent "filled prescriptions written by physicians for the physicians' personal use, in violation of Fla. Stat. § 458.331(r) which prohibits '[p]rescribing, dispensing, or administering any medicinal drug appearing in any schedule set forth in chapter 893 by the physician to himself or herself.'" ALJX 1, at 10. The Show Cause Order also alleged that Respondent "violated Florida law by dispensing controlled substances pursuant to these invalid prescriptions." *Id.* Neither it nor the Government Prehearing Statement, however, specified the provision of the allegedly violated Florida law. The CALJ referenced the corresponding responsibility provision of 21 CFR 1306.04(a) but that, of course, cannot be the provision of "Florida law" that the Show Cause Order referenced.

During the time period covered by the Show Cause Order, Florida law required that a pharmacist, before dispensing a controlled substance listed in schedules II through IV, first determine "in the exercise of her or his professional judgment ... that the order is valid." Fla. Stat. § 893.04(2)(a) (2009). The substances that Respondent admitted dispensing to physicians for their personal use, testosterone and phentermine, were listed in Florida law as controlled substances under schedules III and IV, respectively. Fla. Stat. § 893.03 (2011) ("Standards and schedules"). *See also* Fla. Stat. § 893.02(22) (2011) (defining a "prescription" as an order for drugs "issued in good faith and in the course of professional practice ... and meeting the requirements of s. 893.04.>").

The Respondent's argument against liability was that the Florida statute referenced in the Order to Show Cause was not sufficiently related to preventing the diversion of controlled substances. Resp. Br., at 17-18. According to Respondent, the "primary purpose behind § 458.331 ... is to regulate the practice of medicine and discipline physicians that have engaged in unethical and/or unprofessional behavior." *Id.* at 17. It argued that "[c]learly, the primary purpose behind § 458.331 ... in general and § 458.331(r) specifically is not 'control[ling] the supply and demand of controlled substances in both lawful and unlawful drug markets' ... or preventing drug diversion, but disciplinary actions and remedies against offending physicians." *Id.* at 18 (quoting *Gonzales v. Raich*, 545 U.S. 1, 19 (2005)).

Respondent's argument fails as does its similar argument concerning its admitted interstate shipment of controlled substances in violation of four States' non-resident pharmacy requirements. The Florida statutes at issue concerned exactly what Respondent argued they did not. As the CALJ stated, the Florida provision cited in the Show Cause Order "prohibits an activity that 'increases the opportunity for those persons who are self-abusing or engaged in diversion to obtain controlled substances.'" R.D., at 38 n.159 (citing *Fred Samimi, M.D.*, 79 FR 18,698, 18,710 (2014)). Further, Chapter 893, referenced in the Florida statute listed in the Show Cause Order, is entitled "Drug Abuse Prevention and Control." These provisions of Florida law concern much more than physician discipline; by their very title, they go to the heart of the controlled substance anti-diversion mission – drug abuse prevention and control.

The dilemma posed by this Show Cause Order allegation is whether it, in its and the hearing record's brevity concerning this charge, sufficiently noticed Respondent of the charge being levied against it. The CALJ thought not. *See* R.D., at 39. However, Respondent defended against this charge and, in doing so, purported to understand the charge being levied against it.

I find that neither the Show Cause Order nor the Government Prehearing Statement specified a statutory provision that Respondent allegedly violated.⁴³ 21 CFR 1301.37(c). Thus, even though there is evidence in the record that Respondent violated Florida law when it filled prescriptions for the personal use of the prescriptions' prescribers, I did not consider this evidence when I conducted the public interest analysis of 21 U.S.C. § 823(f).⁴⁴

Other Allegations

Allegation that Respondent Was Unable to Readily Retrieve Prescriptions It Had Dispensed

The Show Cause Order alleged that Respondent was unable to “readily retrieve prescriptions it had dispensed” in violation of 21 CFR 1304.04(h)(3) and (4). ALJX 1, at 7-8. The Show Cause Order cited 12 examples of prescriptions that Respondent allegedly did not retrieve and provide to the DI as required by law.

According to the regulation, which is applicable to inventories and records of controlled substances in schedules III through V, “[p]aper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location ... in such form that they are readily retrievable from the other prescription records of the pharmacy.” 21 CFR 1304.04(h)(4). The regulatory definition of “readily retrievable” calls for locating the records “in a reasonable time.” 21 CFR 1300.01(b). Agency precedent states that “what constitutes ‘a reasonable time’ necessarily depends on the circumstances.” *Edmund Chein, M.D.*, 72 FR 6580, 6593 (2007), *pet. for rev. denied*, *Chein v. Drug Enforcement Admin.*, 533 F.3d 828, 832 n.6 (D.C. Cir 2008), *cert.*

⁴³ Neither did the Government Brief specify a statutory provision that Respondent allegedly violated.

⁴⁴ Fla. Stat. § 458.331(r) (which prohibited “[p]rescribing, dispensing, or administering any medicinal drug appearing in any schedule set forth in chapter 893 by the physician to himself or herself”) in conjunction with Fla. Stat. § 893.04(2)(a) (which prohibited a pharmacist from dispensing a controlled substance without first determining, in the exercise of her professional judgment, that the order was valid).

denied, 555 U.S. 1139 (2009). According to that precedent, “under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request.” *Id.* The decision explained that “[t]o allow a registrant an even greater period of time to produce the records would create an incentive for those who are engaged in illegal activity to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.” *Id.*

As found above, Respondent never provided the 12 requested prescriptions to the DI. Respondent included ten of the 12 prescriptions in an exhibit for the hearing in this proceeding more than two years after the unannounced inspection, but this is insufficient to comply with the “readily retrievable” requirement. As of the final day of the hearing in this proceeding, or about 28 months after the unannounced inspection, Respondent still had not provided the Government with two of the prescriptions. Accordingly, I find that the Government has proved by substantial evidence that Registrant failed to comply with the requirements of 21 CFR 1304.04(h)(3) and (4).

Allegation that Respondent Shipped Controlled Substances Out-of-State Without Complying With Those States’ Non-Resident Pharmacy Requirements

The Order to Show Cause alleged that Respondent shipped controlled substances to customers in Alabama, Illinois, Kentucky, and Vermont without complying with those States’ non-resident pharmacy requirements.⁴⁵ As found above, Respondent shipped controlled

⁴⁵ Alabama (prescription shipped Jan. 14, 2013): Ala. Admin. Code r. 680-X-2-.07(2) (2005) (“No nonresident pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Alabama State Board of Pharmacy.”); Illinois (prescription shipped Jan. 27, 2012): Ill. Admin. Code tit. 68 § 1330.550(a) (2012) (“The Division shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this State that dispense medications for Illinois residents and mail, ship or deliver prescription medications into this State”); Kentucky (prescription shipped March 19, 2012): Ky. Rev. Stat. § 315.0351(1) (2007) (“Every person or pharmacy located outside this Commonwealth which does business, physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth ... shall hold a current pharmacy permit ... issued by the Kentucky Board of Pharmacy.”); and Vermont (prescription

substances to customers in Alabama, Illinois, Kentucky, and Vermont without being licensed in, or permitted by, those States to do so. Accordingly, I find that the Government has proved by substantial evidence that Registrant failed to comply with the non-resident pharmacy requirements of four States.

Respondent admitted that it was not in compliance with any of these four States' non-resident pharmacy requirements when it shipped controlled substances to customers at addresses in those States. Further, Respondent did not challenge the Government's contention that it violated these four States' non-resident pharmacy requirements when it argued that "[i]t should be note [sic] that other than the out-of-state dispensing instances ... [alleged], there was no evidence that ... [Respondent] is engaged in shipping medications to states where it does not hold a Non-resident pharmacy license." Resp. Br., at 9. Instead, Respondent argued that its noncompliance with these four States' non-resident pharmacy statutes was insufficiently related to preventing the diversion of controlled substances to be considered under Factor Four of 21 U.S.C. § 823(f). *Id.* at 4-9 (citing *Fred Samimi*, 79 FR at 18,710). The CALJ disagreed and concluded that the out-of-state pharmacy provisions had a "sufficient nexus" to the Act's "core purpose of preventing drug abuse and diversion to warrant consideration under the Public Interest Factors." R.D., at 43. I agree with the result the CALJ recommended.

The second public interest factor is "experience in dispensing ... controlled substances." 21 U.S.C. § 823(f)(2). "Dispense," according to 21 U.S.C. § 802(10), means "deliver a controlled substance to an ultimate user ... pursuant to the lawful order of ... a practitioner."

shipped Jan. 10, 2013): Vt. Stat. Ann. tit. 26 § 2061(a) (2013) ("All drug outlets shall biennially register with the board of pharmacy."); Vt. Stat. Ann. tit. 26 § 2022(7) (2013) ("Drug outlet' means all pharmacies, ... and mail order vendors which are engaged in dispensing, delivery, or distribution of prescription drugs."); *see also* 20-4-1400 Vt. Code R. § 16.1 *et seq.* (2013) ("Non-resident pharmacy' means a drug outlet ... located outside of Vermont which dispenses prescription drugs ... for Vermont residents ... and which mails, ships, or delivers such prescription drugs ... into this state").

Despite the testimony of Respondent's Owner and PIC and her statements to the DI, Respondent admitted that it "dispensed" controlled substances in violation of four States' legal requirements. Thus, I find that Respondent's experience in dispensing controlled substances includes the dispensing of controlled substances to customers living in four States in which Respondent was not licensed or legally authorized to dispense those controlled substances. *Id.* This result is consistent with Agency precedent. *Sun & Lake Pharmacy, Inc.; d/b/a the Medicine Shoppe*, 76 FR 24,523, 24,532 (2011) (finding that Respondent committed actionable misconduct when it dispensed prescriptions to residents of States in which it was not licensed.). *See also* 21 U.S.C. § 802(21) (defining "practitioner" as meaning, in relevant part, a "pharmacy ... licensed, registered or otherwise permitted ... by the ... jurisdiction in which ... [it] practices ... to ... dispense a controlled substance").

Allegation that Respondent Violated Florida State Law by Failing to Report Some Prescriptions to E-FORCSE in Violation of Florida Statute § 893.055(4)

The Show Cause Order alleged that Respondent failed to comply with Florida State law by not reporting specified prescriptions to E-FORCSE. As discussed above, I found that Respondent did not challenge the Government's assertion that six controlled substance prescriptions it dispensed did not appear in E-FORCSE. The CALJ found "not persuasive" Respondent's argument that the non-reportings "had their genesis in a good-faith technical glitch." R.D., at 46 n.184. He recommended finding the testimony of Respondent's Owner and PIC on this allegation "wholly unpersuasive," "even if assumed, *arguendo*, to be credible." *Id.*

The Florida statute that the Respondent allegedly violated required the reporting to E-FORCSE of each controlled substance dispensed "as soon thereafter as possible, but not more than 7 days after the date the controlled substance is dispensed unless an extension is approved." Fla. Stat. § 893.055(4) (2012). Respondent, a covered "dispenser" under the provision, did not

claim that it had been granted an extension under the statute. Fla. Stat. § 893.055(1)(c) (“Dispenser’ means a pharmacy ... [or] dispensing pharmacist”).

I disagree with Respondent’s claim that the Florida Statute did “not provide for any penalties for non-compliance, partial compliance or reporting errors.” Resp. Br., at 25. To the contrary, the Florida Statute contained a criminal sanction for a willful and knowing failure to report the dispensing of controlled substances. Fla. Stat. § 893.055(9) (2011) (“Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree.”); *see also* Fla. Stat. § 893.13(7)(a)(2) and (c) (2011) (A person who refuses or fails to keep any required record commits a misdemeanor of the first degree for a first violation and a felony of the third degree for a second or subsequent violation).

Based on all of the evidence in the record, I find that Respondent did not comply with the controlled substance reporting requirements of Fla. Stat. 893.055(4). Respondent’s non-compliance is appropriate for consideration under Factor Four. In this case, due to the overwhelming egregiousness of other violations that Respondent committed, my consideration of Respondent’s non-compliance with the controlled substance reporting requirements of Fla. Stat. 893.055(4) did not have a determinative impact on my public interest assessment.

Summary of Factors Two and Four

As discussed above, the Government presented a *prima facie* case that Respondent, with a subjective belief of a high probability that controlled substance prescriptions were not legitimate and while taking deliberate actions to avoid learning of their illegitimacy, filled multiple prescriptions for controlled substances which lacked a legitimate medical purpose. The Government also presented a *prima facie* case that Respondent was unable to readily retrieve

prescriptions it had dispensed, filled controlled substance prescriptions and shipped them without meeting the out-of-state pharmacy requirements of four States, filled controlled substance prescriptions that did not contain all of the required information, and failed to report controlled substance prescriptions to E-FORCSE in violation of Florida law. Thus, I conclude that Respondent engaged in egregious misconduct which supports the revocation of its registration. *See Wesley Pope*, 82 FR 14,944, 14,985 (2017) (collecting cases).

I therefore hold that the Government has established a *prima facie* case that Respondent's continued registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

SANCTION

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to its dispensing and recordkeeping practices and its non-compliance with State laws, the burden shifts to the Respondent to show why its continued registration would nonetheless be consistent with the public interest. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387, *pet. for rev. denied sub nom. Medicine Shoppe-Jonesborough v. Drug Enforcement Admin.*, 300 F. App'x 409 (6th Cir. 2008). Under Agency precedent, the Respondent must "present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration." *Hills Pharmacy*, 81 FR at 49,845 (citing *Medicine Shoppe-Jonesborough*, 73 FR at 387 (quoting *Samuel S. Jackson, D.D.S.*, 72 FR 23,848, 23,853 (2007)) (quoting *Leo R. Miller, M.D.*, 53 FR 21,931, 21,932 (1988))). Moreover, because past performance is the best predictor of future performance, DEA has repeatedly held that when a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for those actions and demonstrate that it will not engage in future misconduct.

East Main Street Pharmacy, 75 FR at 66,162 (quoting *Medicine Shoppe-Jonesborough*, 73 FR at 387); *see also MacKay*, 664 F.3d at 820 (DEA may properly consider whether a physician admits fault in determining if the physician’s registration should be revoked.). That acceptance of responsibility must be unequivocal. *Lon F. Alexander, M.D.*, 82 FR 49,704, 49,728 (2017) (collecting cases).

Moreover, the egregiousness and extent of a registrant’s misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer*, 76 FR 19,386, 19,387-88 (2011) (explaining that a respondent can “argue that even though the Government has made out a prima facie case, his conduct was not so egregious as to warrant revocation”); *Paul H. Volkman*, 73 FR 30,630, 30,644 (2008); *see also Paul Weir Battershell*, 76 FR 44,359, 44,369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and “manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant”); *Gregory D. Owens*, 74 FR 36,751, 36,757 n.22 (2009).

Finally, the Agency has also held that “[n]either Jackson, nor any other agency decision, holds ... that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked” or an application should be denied. *Wesley Pope*, 82 FR 14,944, 14,985 (2017) (quoting *Joseph Gaudio*, 74 FR 10,083, 10,094 (2009) (quoting *Southwood Pharmaceuticals, Inc.*, 72 FR 36,487, 36,504 (2007))). *See also Robert Raymond Reppy*, 76 FR 61,154, 61,158 (2011); *Michael S. Moore*, 76 FR 45,867, 45,868 (2011). This is so both with respect to the respondent in a particular case and the community of registrants. *See Pope*, 82 FR at 14,985 (quoting *Gaudio*, 74 FR at 10,095 (quoting *Southwood*, 71 FR at 36,503)). *Cf. McCarthy v. SEC*, 406 F.3d 179, 188-89 (2d Cir. 2005) (upholding SEC’s

express adoptions of “deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions”).

In this case, the CALJ found that Respondent’s acceptance of responsibility was “limited in scope and can be fairly characterized as minimal.” R.D., at 58. Specifically, the CALJ found that Respondent’s Owner and PIC, on behalf of Respondent, accepted responsibility in “only three carefully circumscribed” areas: (1) that she did not document every single conversation with every single prescriber; (2) that she, as the pharmacist-in-charge, shouldered ultimate responsibility for ensuring required documentation was properly completed; and (3) that Respondent filled controlled substance prescriptions for patients who lived a significant distance from the pharmacy. R.D., at 58.

At the hearing, Respondent’s counsel asked Respondent’s Owner and PIC “[w]hat is it that you’re accepting responsibility for in this case?” Tr. 1025. Respondent’s Owner and PIC testified: “That I don’t have any intention to violate DEA rules.” Tr. 1025. This is in no sense a meaningful acknowledgement of Respondent’s misconduct.

In its Exceptions, Respondent contends that it “accepted responsibility for filling long-distance prescriptions and, as remedial measures, stopped dispensing schedule II substances all together.” Resp. Exceptions, at 8. Respondent also argues that, through Respondent’s Owner and PIC, it “accepted the responsibility for not documenting in every instance, its efforts in resolving the red flags and as [a] remedial measure stated that it ‘document[s] everything that’s possible.’” *Id.* It further contends that, “[a]lthough ... [Respondent’s Owner and PIC] accepted responsibility for the misfiling of the prescriptions, it is easily deuced [sic] from the record and from the instituted corrective measures that the Respondent accepted the responsibility for the missing information as well.” *Id.* at 18 n.19.

I reject Respondent's contentions. Most significantly, Respondent's Owner and PIC has entirely failed to acknowledge that Respondent violated the CSA when it knowingly dispensed numerous controlled substance prescriptions which were clearly issued outside of the usual course of professional practice and which lacked a legitimate medical purpose. And even as to the factual matters for which the CALJ found she accepted responsibility, such as failing to adequately document her conversations with prescribers, Respondent's Owner and PIC immediately equivocated by making excuses for not doing so in the future. She stated, "Now I document every little thing that it's concerned to the conversation and the dispensing of controlled substances. However, there's a lot of conversation going on on a daily basis between doctors and offices." Tr. 1010-11. Similarly, after acknowledging that she filled controlled substance prescriptions for patients who lived a significant distance from the pharmacy, Respondent's Owner and PIC justified her filling of the prescriptions, asserting, without any evidence to corroborate her claim, that "some of them are working locally and they all had a local doctor." *Id.* at 1026.

Respondent's Owner and PIC also testified that, "If the DEA provide me, do not fill for 100 miles, like – that's why I said, I accepted my responsibility, I took remedial measures. I do not fill schedule II prescriptions in my pharmacy because of these conflicting red flags. Because it's a practice of Florida to travel." *Id.* at 1023-24. Respondent characterized this testimony as meaning that Respondent's Owner and PIC accepted responsibility for filling long-distance prescriptions. Resp. Br., at 36; *see also* Resp. Exceptions, at 8. I specifically reject Respondent's argument. Notably, this testimony began with the word "if" and in any event, it does not constitute an acceptance of responsibility for violating the corresponding responsibility rule. Further, the testimony was not offered in the context of addressing Respondent's filling

prescriptions from its Florida customers who travelled long distances to patronize Respondent. Rather, the testimony was offered to address Respondent's filling of prescriptions for out-of-state customers, specifically customers from Kentucky about whom Respondent's Owner and PIC testified she had been "clearly instructed" by DEA. Tr. 1023.

Notably, at no point in the hearing did Respondent's Owner and PIC accept responsibility, let alone accept responsibility unequivocally, for violating the corresponding responsibility regulation. Notably, the testimony of Respondent's Owner and PIC manifests that she still does not acknowledge the scope of a pharmacist's obligation under 21 CFR 1306.04(a). As one example, she testified that "[t]he prescription is an order for the pharmacist to fill. For me not to fill that prescription, I have to have a very good reason not to fill it, because it's an order from the doctor to me to fill that prescription for that patient." *Id.* at 1168. As the Agency has previously recognized, a registrant cannot accept responsibility for its misconduct when it does not even understand what the law requires of it. *Alexander*, 82 FR at 49,729. I agree with the CALJ's conclusion that "there is no unequivocal acceptance of responsibility on this record that would be particularly helpful to the Respondent's efforts to avoid a sanction." R.D., at 58.

Here, the CALJ concluded that "the paltry nature of the Respondent's acceptance of responsibility would have rendered remedial measure evidence largely irrelevant." *Id.* In addition, Respondent's misconduct included an egregious abdication of the corresponding responsibility requirement involving the dispensing of controlled substances such as Dilaudid 8 mg., a most potent and highly abused schedule II drug; the evidence also shows that Respondent committed extensive violations of other Federal and State legal requirements. Thus, due to the Respondent's "paltry" acceptance of responsibility and its "intentional decision to decline to notice evidence of remedial steps" leading to the preclusion of that evidence from consideration,

the CALJ recommended that “the record supports the imposition of a sanction.” *Id.* I find that this is the appropriate result on the record in this case.

I agree with the CALJ’s assessment that, “[w]here no understanding is acquired about how the regulated conduct fell short of professional and federal and state legal standards, it would be difficult (even illogical) to predict improvement.” *Id.* at 59. I also agree with the CALJ’s prediction that Respondent “is likely to proceed in the future as it has in the past if not curtailed in its ability to do so.” *Id.* I further agree with the CALJ that the “sheer number of established transgressions of various types, coupled with the refusal to admit that issues existed, would render a sanction less than revocation as a message to the regulated community that due diligence is not a required condition precedent to operating as a registrant.” *Id.*

Respondent has not rebutted the Government’s *prima facie* showing that its continued registration is “inconsistent with the public interest.” 21 U.S.C. § 823(f). I will therefore order that Respondent’s registration be revoked and that any pending applications be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 824(a) and 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FP1049546 issued to Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy be, and it hereby is, revoked. I further order that any pending application of Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy for renewal or modification of this registration be, and it hereby is, denied. This order is effective [insert Date Thirty Days From the Date of Publication in the Federal Register.]

Date: February 28, 2018.

Robert W. Patterson,
Acting Administrator.

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